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A Case at a Crossroad:
United States ex rel. Franklin v. Parke-Davis
and the Intersection of Regulating Promotion of Off-Label Uses and Medicaid Fraud and

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ABSTRACT

In *United States ex rel. Franklin v. Parke-Davis*, a former employee of a pharmaceutical manufacturing company alleged violations of the federal False Claims Act stemming from the company's promotion of an FDA-approved drug for an unapproved use. The suit presented a novel legal claim that brought together two otherwise distinct elements of food and drug law – the regulation of promotion of off-label uses of approved drugs and the prosecution of Medicare and Medicaid fraud and abuse via the federal False Claims Act. This paper examines individually each of these areas of food and drug law and then turns to the conjunction between the two created by the lawsuit. The paper concludes with a discussion of the potential policy ramifications of a decision in *United States ex rel. Franklin v. Parke-Davis*.

I. Introduction

On August 13, 1996, David Franklin filed a nine-count action against Parke-Davis, a pharmaceutical manufacturing company, alleging violations of the federal False Claims Act stemming from the company's promotion of an FDA-approved drug for an unapproved, or off-label, use.¹ Franklin's suit presented a novel legal claim that brought together two otherwise distinct elements of food and drug law – the regulation of promotion of off-label uses of approved drugs and the enforcement of the Medicare and Medicaid fraud and abuse laws via the federal False Claims Act. *United States ex rel. Franklin v. Parke-Davis* thus provides an ideal lens for independently examining these two elements of food and drug law, which have been the subjects of extensive scholarly investigation. Furthermore, *Franklin v. Parke-Davis* creates a fascinating collision between these two elements of food and drug law, leading to interesting legal and policy considerations.

This paper seeks to explore the two areas of food and drug law that collided in *Franklin v. Parke-Davis* – regulation of off-label uses and Medicare and Medicaid fraud and abuse laws – as well as the conjunction of the two. Part II of the paper details the FDA's traditional and current approaches to regulating promotion of off-label uses of approved drugs. Part III addresses the Medicare and Medicaid fraud and abuse laws, particularly the federal False Claims Act and its qui tam provision, as well as the statutory provisions of the Medicare and Medicaid laws pertaining to prescription drug coverage. Part IV provides an in-depth examination of the facts and legal theories involved in *Franklin v. Parke-Davis*, as well as a focus on those legal questions that may prove essential in future cases based on similar claims. Finally, Part V highlights some potential policy ramifications of a decision in *Franklin v. Parke-Davis* that may influence a court's decision in a similar future case.

II. Regulation of Promotion of Off-Label Uses of Approved Drugs

¹United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 46 (D.Mass. 2001).

FDA's Traditional Approach:

FDA's traditional approach to regulating off-label use of approved drugs, which prevailed until the passing of the Food and Drug Administration Modernization Act of 1997, differentiated between three types of activities – (1) off-label prescriptions by physicians, (2) marketing and promotion of off-label uses by drug manufacturers, and (3) scientific discussion of off-label uses by third-parties. While FDA flatly prohibits manufacturers from promoting an approved drug for unapproved uses, the agency has traditionally recognized physician prescribing habits as a component of the doctor-patient relationship, and thus has not interpreted off-label prescriptions as violations of the FD&C Act.² As physicians are free to prescribe approved drugs for off-label uses, FDA acknowledges that “physicians need reliable and up-to-date information concerning off-label uses” and that this information comes from a variety of sources.³ FDA has therefore not sought to restrict scientific discussion of off-label uses that is truly independent from the influence of the drug manufacturer, which is usually disseminated in the form of “enduring materials” or CME seminars.⁴

Off-Label Prescriptions by Physicians

“Off-label use” by physicians has been defined to include using an approved drug to treat a disease that is not indicated on its label but is closely related to an indicated disease, using an approved drug to treat unindicated diseases, and treating the indicated disease, but varying from the indicated dosage, regimen or patient population.⁵ Physician prescription of off-label uses of FDA-approved drugs is an “established

²PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW: CASES AND MATERIALS* 620 (2d Ed. 1991).

³Washington Legal Foundation v. Friedman, 13 F.Supp. 2d 51, 56 (D.D.C. 1998) (quoting deposition of William K. Hubbard, Associate Commissioner for Policy Coordination at 62-63).

⁴*Id.*

⁵A. Elizabeth Blackwell & James M. Beck, *Drug Manufacturers' First Amendment Right to Advertise and Promote Their Products for Off-Label Use: Avoiding a Pyrrhic Victory*, 58 FOOD & DRUG L.J. 439, 440 (2003).

aspect of the modern practice of medicine.”⁶ The precise extent of off-label use is not firmly established, although some estimates state that between 25 and 65% of all prescriptions written are for an off-label use.⁷ Off-label use is extremely prevalent in specific areas of medicine, particularly in oncology and pediatrics.⁸ The General Accounting Office found that 25% of anti-cancer drugs were prescribed off-label and 56% of cancer patients were given at least one drug off-label.⁹

FDA has long taken the position that, “once a [drug] product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in the approved labeling.”¹⁰ FDA first established this policy in a Notice of Proposed Rulemaking published in the Federal Register in 1972, which explained that the requirements of the FD&C Act’s new drug provisions were satisfied if an approved new drug was shipped in interstate commerce with the approved package insert and neither the shipper nor the recipient intended that it be used for an unapproved purpose.¹¹ Once the approved drug reached local pharmacies after interstate shipping, a physician could prescribe it for any medical condition without considering whether FDA had determined the drug to be safe and effective with respect to that illness, and without informing or obtaining the approval of FDA.¹² FDA has traditionally taken this position because it recognizes that curtailing doctors’ ability to prescribe drugs for off-label uses constitutes an interference with medical practice as between the physician and patient. Such interference has

⁶WLF v. Friedman, 13 F. Supp. 2d at 56 (citing “Off-Label Drugs, Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies,” GAO/PEMD-91-14 at 5 (Sept. 1991)).

⁷Blackwell & Beck, *supra* note 5, at 440 (citing Shane M. Ward, *WLF and the Two-Click Rule: The First Amendment Iniquity of the Food and Drug Administration’s Regulation of Off-Label Drug Use Information on the Internet*, 56 FOOD & DRUG L.J. 41, 45-46 (2001)).

⁸WLF v. Friedman, 13 F. Supp. 2d at 56.

⁹*Id.* (citing “Off-Label Drugs, Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies,” GAO/PEMD-91-14 at 4 (Sept. 1991)).

¹⁰Citizen Petition Regarding the Food and Drug Administration’s Policy on Promotion of Unapproved Drugs and Devices; Request for Comments, 59 Fed. Reg. 59820, 59821 (Nov. 18, 1994).

¹¹Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration: Notice of Proposed Rulemaking, 37 Fed. Reg. 16,503, 16,503 (Aug. 15, 1972).

¹²Legal Status of Approved Labeling for Prescription Drugs, 37 Fed. Reg. at 16,503; WLF v. Friedman, 13 F. Supp. 2d at 55.

never been authorized by Congress, which declined to provide legislative restrictions on the medical profession because of a patient's right to seek civil damages in the courts if there is evidence of malpractice.¹³ FDA therefore does not consider physicians to violate the FD&C Act by prescribing drugs for off-label uses; however physicians may violate the Act by distributing either approved or unapproved drugs for unapproved uses. A physician acting as a distributor of a drug is fully subject to the requirements of §505 of the FD&C Act.¹⁴

Manufacturer Promotion of Off-Label Uses

While FDA has consistently taken the position that physicians may freely prescribe approved drugs for off-label uses, the agency's traditional approach to manufacturer promotion of such uses has been much more restrictive. In its 1972 Notice, FDA stated:

where a manufacturer or his representative, or any person in the chain of distribution, does anything that directly or indirectly suggests to the physician or to the patient that an approved drug may properly be used for unapproved uses for which it is neither labeled nor advertised, that action constitutes a direct violation of the Act and is punishable accordingly...¹⁵

FDA control of manufacturer promotion of off-label use has historically come in two forms: (1) federal regulations that explicitly prohibit manufacturers from suggesting off-label uses in any advertisement for a prescription medical product; and (2) using manufacturer promotions as a basis for finding that the manufacturer either placed an unapproved new drug in interstate commerce or finding that a product is misbranded.¹⁶

¹³United States v. Evers, 453 F. Supp. 1141, 1149 (M.D.Ala. 1978).

¹⁴HUTT AND MERRILL, *supra* note 2, at 622 n.8.

¹⁶Blackwell & Beck, *supra* note 5, at 441.

FDA regulations specifically state, “An advertisement for a prescription drug . . . shall not recommend or suggest any use that is not in the labeling accepted in such approved new-drug application or supplement.”¹⁷ FDA traditionally defined advertising very broadly, interpreting “the term ‘advertisement’ to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product.”¹⁸ Based on this broad definition, FDA prohibited virtually any statement by a manufacturer “recommending or suggesting” an off-label use for one of its products.¹⁹

FDA also traditionally restricted manufacturer speech promoting off-label use through its enforcement of non-speech related conduct regulations. This approach has come under extensive First Amendment scrutiny in recent years, which has led the agency to modify this policy, as discussed below. However, FDA has traditionally regulated manufacturer promotion of off-label uses through enforcement of both the “new drug” approval requirements and the prohibition against misbranding. FDA has taken the position that manufacturers violate the FD&C Act by engaging in interstate commerce in an approved new drug for an off-label use. §505(a) of the FD&C Act provides, “No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed [with the Food and Drug Administration] . . . is effective with respect to such drug.”²⁰ Armed with this statutory provision, FDA reasoned that an approval of a new drug application for interstate distribution can only become effective as to the particular use or uses identified in the application. “Thus, an approved new drug that is marketed for a “new use” [off-label use] becomes an unapproved new drug with respect to that use.”²¹

FDA has also contended that an approved new drug that is marketed for an off-label use is “misbranded”

¹⁷Prescription-drug Advertisements, 21 C.F.R. §202.1(e)(4)(i)(a) (2004).

¹⁸Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074, 64,076 (Dec. 3, 1997).

¹⁹Blackwell & Beck, *supra* note 5, at 441.

²⁰21 U.S.C. §355(a) (2004).

²¹Decision in *Washington Legal Foundation v. Henney*, 65 Fed. Reg. 14,286, 14,286 (Mar. 16, 2000).

under the FD&C Act because the drug’s labeling does not include “adequate directions for use,” as required by §502(f) of the Act.²² The agency’s position has been that:

All drugs and devices must bear labeling with adequate directions for each intended use. If labeling for a drug or device fails to contain adequate directions for *each intended use*, the drug or device is deemed to be misbranded (section 502(f)(1) or the act).²³

FDA has interpreted “intended use” to refer to the objective intent of the persons legally responsible for the labeling of the product, as shown by the circumstances surrounding the distribution.²⁴ Furthermore, “[the] intended use or uses of a drug...may ...be determined from advertisements, promotional material, oral statements by the product’s manufacturer or its representatives, and any other relevant source.”²⁵ Thus, virtually any promotion of off-label use may demonstrate the existence of an “intended use” for which instructions are not included in the product labeling, rendering the product misbranded.²⁶

If FDA determines that a manufacturer has violated either the “new drug” approval requirements of §505(a) of the FD&C Act or the “misbranding” prohibitions of §502(f) of the Act, it has a number of enforcement options available under the Act. The agency may seize the approved drug, and “may seek an injunction against, or criminal prosecution of, those responsible for introducing such a product into commerce.”²⁷ Until recently, FDA has contended that it may use a manufacturer’s promotional speech as evidence that a manufacturer is engaging in conduct prohibited by the FD&C Act, which may subject the manufacturer to the Act’s enforcement provisions.²⁸ However, as discussed below, this contention has become much more tenuous in light of the decisions in *Washington Legal Foundation v. Friedman* and its progeny, discussed

²²*Id.*, see also Blackwell & Beck, *supra* note 5, at 443.

²⁴*Id.*

²⁵Decision in *Washington Legal Foundation v. Henney*, 65 Fed. Reg. at 14,286.

²⁶Blackwell & Beck, *supra* note 5, at 444.

²⁷Decision in *Washington Legal Foundation v. Henney*, 65 Fed. Reg. at 14,286-87 (citing 21 U.S.C. §§ 332, 333).

²⁸Blackwell & Beck, *supra* note 5, at 445.

below.

Third-Party Speech Promoting Off-Label Use

In addition to allowing doctors to prescribe approved drugs for off-label uses, FDA has never sought to restrict the ability of third-parties to publish and disseminate scientific information about off-label uses. Indeed, as discussed above, FDA has repeatedly recognized the importance of “open dissemination of scientific and medical information regarding these treatments.”²⁹ FDA has, however, traditionally viewed manufacturer dissemination of such materials as promotion that constitutes advertising and thus violates the FD&C Act.³⁰ FDA regulation in this area has focused on “determining whether an industry-supported activity is independent and not generally subject to regulation,” as opposed to manufacturer-supported and therefore regulated.³¹ It is in providing guidance on this issue that FDA’s policies have changed most dramatically in recent years, particularly in response to First Amendment criticisms.

Recent Changes to FDA’s Approach:

Pre-FDAMA Guidances

For more than two decades, FDA pursued the enforcement policy discussed above regarding off-label uses of approved drugs. FDA focused its enforcement efforts on curtailing manufacturers’ ability to promote off-label uses of their drugs, believing that the speech contained in promotional materials could properly be cabined if it were shown to be evidence that a manufacturer either placed an unapproved new drug in interstate commerce or that the product was misbranded. The agency did not attempt to interfere with physicians’ prescriptions of approved drugs for off-label uses, nor did it pursue actions against third parties who disseminated scientific information about off-label uses, recognizing the value of such scientific information to

²⁹WLF v. Friedman, 13 F. Supp. 2d at 56.

³⁰Final Guidance on Industry-Supported Scientific and Educational Activities , 62 Fed. Reg. at 64,076.

³¹*Id.*

the medical community. However, FDA faced a challenge because the pharmaceutical industry traditionally played a large role in supporting the dissemination of scientific information to medical professionals through reprints of journal articles and reference texts (“enduring materials”).³²

In 1996, FDA published two Guidances entitled “Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data” and “Guidance for Industry Funded Dissemination of Reference Texts.”³³ These Guidances related to the dissemination, by drug sponsors, of reprints of journal articles and reference texts (“enduring materials”) when the publications address off-label uses for the company’s previously approved products.³⁴ In these Guidances, FDA noted the need to “strike the proper balance between the need for an exchange of reliable scientific data and information within the health care community, and the statutory requirements that prohibit companies from promoting products for unapproved uses.”³⁵ The Guidances therefore described the circumstances under which FDA intended to allow dissemination of enduring materials to health care professionals.³⁶

³²Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. at 64,076.

³³Advertising and Promotion; Guidances, 61 Fed. Reg. 52,800, 52,800 (Oct. 8, 1996).

³⁴WLF v. Friedman, 13 F. Supp. 2d at 58.

³⁵Advertising and Promotion; Guidances, 61 Fed. Reg. at 52,800.

³⁶*Id.* Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data required that: (1) The principal subject of the article be the FDA-approved use, (2) The article be published in accordance with the regular peer-review procedure of the journal in which it was published, (3) the article should report the original study that was represented by the sponsor, submitted to the FDA, and accepted by the agency as one of the adequate and well-controlled studies providing evidence of effectiveness, (4) The reprint should be from a bona fide peer-reviewed journal, (5) If the article contains effectiveness rates, data, analyses, uses, regimens, or other information that is different from approved labeling, the reprint should prominently state the difference(s), with specificity, on the face of the reprint, and (6) The reprint should disclose all material facts and should not be false or misleading. *Id.* at 52801. Guidance for Industry Funded Dissemination of Reference Texts required that: (1) The reference text should not have been written, edited, excerpted, or published specifically for, or at the request of, a drug... firm, unless the text was prepared in a manner that results in a balanced presentation of the subject matter, (2) The content of the reference text should not have been reviewed, edited, or significantly influenced by a drug... firm, or agent thereof, unless the text was prepared in a manner that results in a balanced presentation of the subject matter, (3) The reference text should not be distributed only or primarily through drug... firms, (4) The reference text should not focus primarily on any particular drug(s)... of the disseminating company, nor should it have a significant focus on unapproved uses of the drug(s) marketed or under investigation by the firm supporting the dissemination of the text, (5) Specific product information (other than the approved package insert) should not be physically appended to the reference text, and (6) A drug... company representative should not refer to, or otherwise promote, in any manner or at any time, information in the reference text that is not consistent with the approved labeling for a product. *Id.* The second Guidance also provided an exception for reference texts written, edited, or published by a sponsor or agent of a sponsor..., where the authorship, editing, and publishing of the reference text results in a balanced presentation of the subject matter, for which FDA would allow distribution of a reference text in the circumstances described in paragraphs 3 through 6. *Id.*

Also, in the late 1980s, drug companies greatly increased the resources they devoted to sponsoring Continuing Medical Education (“CME”) seminars.³⁷ Congress became concerned with the promotional practices of drug manufacturers, and conducted hearings in 1990 to investigate the matter.³⁸ These hearings eventually led FDA to publish a “Guidance for Industry on Industry-Supported Scientific and Educational Activities” in 1997.³⁹ This Guidance attempted to provide guidelines for distinguishing between activities on behalf of companies that market products and activities, supported by companies, but otherwise independent from promotional influence of the supporting company.⁴⁰ The agency recognized that industry-supported activities could be both nonpromotional and educational, but noted that “demarcating the line between activities that are performed by or on behalf of the company, and thus subject to regulation, and activities that are essentially independent of their influence” had become more difficult given industry’s increasing role in supporting CME.⁴¹ FDA provided a list of twelve factors that the agency would consider as part of an overall evaluation of “whether and to what extent the company is in a position to influence the presentation of information related to its products or otherwise transform an ostensibly independent program into a promotional vehicle.”⁴²

FDAMA Changes to FDA Policy

On November 21, 1997, President Clinton signed into law the Food and Drug Administration Modernization

³⁷WLF v. Friedman, 13 F. Supp. 2d at 57.

³⁸*Advertising, Marketing and Promotional Practices of the Pharmaceutical Industry, 1990: Hearing Before the Senate Committee on Labor and Human Resources*, 101st Cong. 2, 5, 8-13 (1990).

³⁹WLF v. Friedman, 13 F. Supp. 2d at 57.

⁴⁰Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. at 64,094.

⁴¹*Id.* at 64,095.

⁴²*Id.* These factors included: (1) Control of Content and Selection of Presenters and Moderators; (2) Disclosures; (3) The Focus of the Program; (4) Relationship Between Provider and Supporting Company; (5) Provider Involvement in Sales or Marketing; (6) Provider’s Demonstrated Failure to Meet Standards; (7) Multiple Presentations; (8) Audience Selection; (9) Opportunities for Discussion; (10) Dissemination; (11) Ancillary Promotional Activities; and (12) Complaints. *Id.* at 64,097-99.

Act of 1997 (“FDAMA”), which amended the FD&C Act. The provisions of §401 of the FDAMA perpetuated in part and modified in part the policies contained in the FDA Guidances on enduring materials, to permit “manufacturer distribution of written information concerning the safety, effectiveness or benefit of an unapproved use of a previously approved drug under specified conditions.”⁴³ With the passage of the FDAMA, Congress cabined FDA’s ability to curtail dissemination of certain enduring materials concerning off-label uses by drug manufacturers who meet the specified conditions. If a manufacturer meets the specified conditions, FDA may not use its dissemination as evidence of the manufacturer’s intent that its product be used for an off-label use.⁴⁴ As the FDA explained, “if section 401 did not exist, the government could use such dissemination as evidence in establishing a manufacturer’s illegal distribution of a new drug or device for a “new use,” and in establishing that the product is misbranded.”⁴⁵ The FDAMA does not address CME seminars, thus the 1997 “Guidance for Industry on Industry-Supported Scientific and Educational Activities” still embodies the FDA’s current policy on that issue.

Under the FDAMA and the FDA’s implementing regulations, drug manufacturers may distribute particular enduring materials, including scientific or medical studies from peer-reviewed journals or scientifically sound “reference publications,” which is defined as medical textbooks and a narrow class of other non-articles, if they are free from influence by the product sponsor.⁴⁶ Manufacturers may not distribute such enduring materials to patients, but may distribute such information to physicians, HMOs, pharmacy benefit managers, government bodies, and insurers, provided they meet the other requirements of the Act in doing so.⁴⁷ These requirements include:

⁴³Washington Legal Foundation v. Henney, 56 F. Supp. 2d 81, 83 (D.D.C. 1999); WLF v. Friedman, 13 F. Supp. 2d at 58.

⁴⁴Decision in Washington Legal Foundation v. Henney, 65 Fed. Reg. at 14,287.

⁴⁵*Id.*

⁴⁶JAMES T. O’REILLY, FOOD AND DRUG ADMINISTRATION § 15:14:50(2d ed. 2003); 21 U.S.C. §§360aaa-1(a), (b) (2004).

⁴⁷21 U.S.C. §360aaa(a).

- (1) Any product on which a manufacturer provides enduring materials must have in effect an approved NDA, PMAA, 510(k) or biologics license;⁴⁸
- (2) The disseminated information must be unabridged, not false or misleading, and not pose a significant risk to the public health;⁴⁹
- (3) The information disseminated may not be derived from clinical research conducted by another manufacturer without that manufacturer's permission;⁵⁰
- (4) FDA must receive an advance copy of the information for review 60 days before the claim is made;⁵¹
- (5) The manufacturer must submit a supplemental new drug application for the off-label use or have certified that such an application will be filed within the applicable statutory deadline;⁵²
- (6) The disseminated information must include prominent disclosure that a) the material concerns an off-label use not approved by the FDA; b) the material is disseminated at the manufacturer's expense; c) identifies the authors of the information who have a financial relationship to the manufacturer; d) includes the product's current officially-approved labeling; e) includes (if applicable) a statement that there are products that have been approved for the particular intended use; f) identifies the person providing funding for a study of the off-label use; and g) provides a bibliography of other articles concerning the off-label use.⁵³

After meeting these conditions and disseminating enduring materials, the manufacturer must continue to prepare and submit semi-annually to the FDA lists of the articles and reference publications disseminated and the categories of recipients.⁵⁴ Furthermore, FDA can force dissemination at the same time of additional information from publications or "any information that the Secretary has authority to make available to the public," in order to provide an objective and balanced presentation of information on the off-label use.⁵⁵ Finally, under the FDAMA, Congress limited the remedies available to FDA to stop the flow of enduring materials. FDA can only order a set of corrective materials to be submitted if it finds "significant risk to the public health" or can order a manufacturer to cease the dissemination of information if the Secretary

⁵⁴21 U.S.C. §360aaa-2.

⁵⁵21 U.S.C. §360aaa(c)(2).

determines that the information being disseminated does not comply with the requirements of the FDAMA.⁵⁶

Washington Legal Foundation v. Friedman and its Progeny

In 1997, Washington Legal Foundation filed suit against the Acting Commissioner of the Food and Drug Administration and the Secretary of the Department of Health and Human Services, alleging that §401 of the FDAMA and the three FDA guidance documents (discussed above) violated the First Amendment. This suit led to a number of decisions by the United States District Court for the District of Columbia addressing the compatibility of the FDA's policies on manufacturer promotion of off-label uses with the First Amendment. The first district court opinion granted Washington Legal Foundation's motion for summary judgment, finding that FDA's three guidance documents, as they existed in 1997, violated the First Amendment.⁵⁷ The district court subsequently issued an opinion clarifying that its opinion on summary judgment only applied to unapproved uses of drugs approved by FDA for other purposes.⁵⁸ After the FDAMA superseded the two FDA Guidances on enduring materials, the district court reviewed its decision on summary judgment in a subsequent opinion, *Washington Legal Foundation v. Henney*, again finding that the FDAMA and the FDA Guidance on CME violated the First Amendment.⁵⁹ Finally, the DC Circuit Court of Appeals vacated the district court's opinion insofar as it found the relevant provisions of the FDAMA and the CME Guidance in violation of the First Amendment.⁶⁰ After the Court of Appeals' opinion, WLF returned to the district court on remand and asked the court to confirm and enforce its original injunction; the court declined to do so, however, because it found that the injunction had been wholly vacated by the Court of Appeals' opinion.⁶¹

⁵⁶21 U.S.C. §360aaa-4.

⁵⁷WLF v. Friedman, 13 F. Supp. 2d at 72.

⁵⁸Washington Legal Foundation v. Friedman, 36 F. Supp. 2d 418, 418 (D.D.C. 1999).

⁵⁹WLF v. Henney, 56 F. Supp. 2d at 87.

⁶⁰Washington Legal Foundation v. Henney, 202 F.3d 331, 337 (D.C. Cir. 2000).

⁶¹Washington Legal Foundation v. Henney, 128 F. Supp. 2d 11, 15 (D.D.C. 2000).

In the first district court opinion on WLF’s motion for summary judgment, the court initially acknowledged that FDAMA §401 would supersede the two FDA Guidances on enduring materials, but continued to find that the three FDA Guidances were incompatible with the First Amendment.⁶² The district court quickly rejected the FDA’s contentions that the Guidance Documents restrained conduct rather than speech and that the speech in question fell outside of the protection of the First Amendment because of the extensive regulation of the food and drug industry.⁶³ Instead, the district court determined that the manufacturer speech in question was properly considered commercial speech, entitled to a reduced degree of First Amendment protection, because the manufacturer sought to promote and induce the purchase of its product through its speech.⁶⁴ Although the manufacturer speech involved was of a scientific nature, typically considered at the core of First Amendment protection, the district court found scientific information disseminated by drug manufacturers to be a particularly important and prevalent marketing tool.⁶⁵ The court cited “the potential to mislead, and the harm that could result” as further support for characterizing the manufacturer speech in question as commercial speech.⁶⁶

Having determined that the manufacturer speech was commercial in nature, the district court went on to apply the *Central Hudson* four-prong test for commercial speech, which requires a court to analyze four elements: (1) the commercial speech “must concern lawful activity and not be misleading;” (2) the proposed speech regulation must be supported by a “substantial” government interest; (3) the restriction must directly and materially advance the government’s interest; and (4) the restriction must be narrowly tailored so as

⁶²WLF v. Friedman, 13 F. Supp. 2d at 74.

⁶³*Id.* at 59-60.

⁶⁴*Id.* at 64.

⁶⁵*Id.*

⁶⁶*Id.* at 65.

to not be “more extensive than is necessary” to serve the government interest.⁶⁷ The district court flatly rejected FDA’s argument that manufacturer speech concerning off-label uses is inherently unlawful because it has not yet met with FDA approval, asserting that by making this argument, “FDA exaggerate[d] its overall place in the universe.”⁶⁸

In considering the second prong of the *Central Hudson* analysis, the district court distinguished between the two interests asserted by FDA: (1) ensuring that physicians receive accurate and unbiased information so that they may make informed prescription choices, and (2) providing manufacturers with ample incentive to get previously unapproved uses on label. The district court dismissed the first asserted interest, stating that “to endeavor to support a restriction upon speech by alleging that the recipient needs to be shielded from that speech for his or her own protection” is “wholly and completely unsupportable.”⁶⁹ As to the second asserted interest, however, the district court found that there was sufficient evidence that dissemination of scientific information to physicians on a drug’s off-label uses has a positive effect upon sales of the drug, such that making ability to disseminate information on off-label use contingent upon FDA approval of that use would encourage manufacturers to obtain FDA approval.⁷⁰ The district court thus found a “substantial government interest” as contemplated by *Central Hudson*.⁷¹ The district court then found that the Guidance Documents directly advanced this substantial government interest in requiring manufacturers to submit supplemental applications to obtain approval for new use because constraining marketing options provided manufacturers with an incentive to get new uses on-label.⁷²

⁶⁷Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York, 447 U.S. 557, 566 (1980).

⁶⁸WLF v. Friedman, 13 F. Supp. 2d at 66-67.

⁶⁹*Id.* at 69-70.

⁷⁰*Id.* at 70-71.

⁷¹*Id.* at 71.

⁷²*Id.* at 72.

When the district court turned to the fourth *Central Hudson* prong, however, it determined that the Guidance Documents were unconstitutional because they contained restrictions that were considerably more extensive than necessary to further the substantial governmental interest in encouraging manufacturers to get new uses on-label.⁷³ The court pointed to less-burdensome alternatives to the Guidances' restrictions as evidence that they were overly extensive, specifically noting that "full, complete, and unambiguous disclosure by the manufacturer" might more precisely serve the government's substantial interest.⁷⁴ Having determined that the Guidances did not comply with the First Amendment, the district court "enjoined FDA from 'in any way . . . limiting any pharmaceutical . . . manufacturer' from 'disseminating' specified journal articles or medical texts and from 'suggesting content or speakers' to an 'independent program provider' in connection with a seminar or symposium funded by the manufacturer."⁷⁵

The district court reviewed its decision in *Washington Legal Foundation v. Friedman* in light of the passage of the FDAMA in 1997 to determine whether the FDA's policies, as embodied in the FDAMA, were unconstitutional.⁷⁶ In this district court proceeding, *Washington Legal Foundation v. Henney*, FDA took the position that a manufacturer violated the FD&C Act by disseminating enduring materials, unless those materials met the requirements of §401 of the FDAMA, and that such violations were actionable by the FDA.⁷⁷ The district court again applied the *Central Hudson* analysis and determined that the FDAMA, like the Guidance Documents, was unconstitutional because its regulations burdened significantly more speech than necessary to advance the government's substantial interest.⁷⁸

⁷³*Id.* at 73.

⁷⁴*Id.*

⁷⁵Decision in *Washington Legal Foundation v. Henney*, 65 Fed. Reg. at 14,287 (citing *WLF v. Henney*, 56 F. Supp. 2d at 88-89).

⁷⁶*WLF v. Henney*, 56 F. Supp. 2d at 84.

⁷⁷*Id.* at 83.

⁷⁸*Id.* at 87.

On February 11, 2000, however, the Court of Appeals for the District of Columbia vacated the district court's decisions and injunctions insofar as they declared §401 and the CME guidance document unconstitutional.

⁷⁹ The Court of Appeals' decision was based on FDA's reversal of its position regarding the independent enforceability of §401 of the FDAMA; after losing in the district court, FDA contended on appeal that a drug manufacturer's noncompliance with §401 does not, by itself, constitute a violation of the law, although a manufacturer who disregards the conditions of the FDAMA safe harbor might be liable in some fashion if it breached an agreement with the Secretary pursuant to that section.⁸⁰ Furthermore, FDA asserted a similar position regarding the legal effect of the CME Guidance, while claiming that it retained the prerogative to use promotional conduct as *evidence* in a misbranding or "intended use" enforcement action.⁸¹

The D.C. Circuit found that there was no case or controversy to provide a basis for WLF's facial First Amendment challenge, given FDA's interpretation that:

(1) §401 provides a 'safe harbor' ensuring that certain forms of conduct [will] not be used against manufacturers in misbranding and 'intended use enforcement actions' based on pre-FDAMA enforcement authority, and (2) neither FDAMA nor the CME Guidance Document 'independently authorizes the FDA to prohibit or sanction speech.'⁸²

As WLF expressly agreed that FDA could proceed on a case-by-case basis under pre-FAMA enforcement authority, the D.C. Circuit found that there was no constitutional controversy between the parties that remained to be resolved, and declined to rule on the constitutionality of a hypothetical interpretation of the statute.⁸³

⁷⁹WLF v. Henney, 202 F.3d at 337.

⁸⁰*Id.* at 335-36.

⁸¹*Id.*

⁸³WLF v. Henney, 202 F.3d at 336.

In a subsequent Notice printed in the Federal Register, FDA clarified that the position it asserted on appeal in *Washington Legal Foundation v. Henney* represented the agency's current approach to regulating manufacturer speech on off-label uses.⁸⁴ The agency explained that FDAMA and its implementing regulations constitute a "safe harbor" for a manufacturer that complies with them in disseminating enduring materials.⁸⁵ "If a manufacturer does not comply, FDA may bring an enforcement action under the FDCA, and seek to use journal articles and reference texts disseminated by the manufacturer as evidence that an approved product is intended for a 'new use.'"⁸⁶ However, FDA will only use a manufacturer's dissemination as evidence in a misbranding suit if the manufacturer has taken itself out of the safe harbor by disseminating in a way contrary to the FDAMA.⁸⁷ The key distinction is that "FDA's prosecutorial power flows from its long-established authority to prosecute manufacturers for misbranding, *not* from the newly created FDAMA."⁸⁸ The FDA expressed a similar interpretation regarding CME.⁸⁹ The 1997 Guidance details the factors FDA will take into account in exercising its enforcement discretion, but the document "does not itself have the force and effect of law."⁹⁰

After FDA published this Notice in the Federal Register, WLF returned to the district court on remand, asking the court to "confirm and enforce [its] continuing injunction" of July 28, 1999 (the initial injunction issued in *Washington Legal Foundation v. Friedman*).⁹¹ WLF argued that FDA's statement in the Notice that the agency may, when appropriate, "proceed, in the context of a case-by-case enforcement, to determine from a manufacturer's written materials and activities how it intends that its products be used" violated the district court's July 28, 1999 injunction.⁹² Although the Court of Appeals had indicated that "part of

⁸⁴Decision in *Washington Legal Foundation v. Henney*, 65 Fed. Reg. at 14,287.

⁸⁵*Id.*

⁸⁶*Id.*

⁸⁷*Washington Legal Foundation v. Henney*, 128 F. Supp. 2d at 13.

⁸⁸*Id.* (emphasis in original).

⁸⁹Decision in *Washington Legal Foundation v. Henney*, 65 Fed. Reg. at 14,287.

⁹⁰*Id.*

⁹¹*WLF v. Henney*, 128 F. Supp. 2d at 13-14.

⁹²*Id.* at 13.

[the district court's] injunction still stands," the district court interpreted that statement as referring only to any parts of the injunction that were not constitutionally based.⁹³ The district court found that its July 28, 1999 injunction was entirely based on the United States Constitution, and therefore "the injunction was wholly vacated as to the FDAMA and the CME Guidelines."⁹⁴ As a result, "there [was] nothing for the Notice to violate," and the court rejected WLF's motion to confirm the injunction.⁹⁵ The district court's decision on remand thus clarified that the Court of Appeals' decision was controlling as to the entire scope of the issue.

In addition to denying WLF's motion to confirm its injunction, the district court expressed frustration that "[a]fter six years' worth of briefs, motions, opinions, Congressional acts, and more opinions, the issue remains 100% unresolved, and the country's drug manufacturers are still without clear guidance as to their permissible conduct."⁹⁶ Since the district court's decision on remand, FDA has issued numerous Warning Letters and Untitled Letters to pharmaceutical manufacturers indicating that they are engaging in promotion of unapproved uses of their drugs through disseminations of information.⁹⁷ In these Warning Letters and Untitled Letters, FDA has identified the promotional materials that purportedly violate the FD&C Act and requested that the manufacturers immediately cease dissemination of those materials and other similar materials.⁹⁸ FDA has further requested that the manufacturers "disseminate accurate and complete information to the audiences that received the misleading messages," and that the manufacturers respond in writing to FDA with a description of their plan for compliance.⁹⁹ These Warning Letters and Untitled Letters have not,

⁹³*Id.* at 14 (citing *WLF v. Henney*, 202 F.3d at 337).

⁹⁴*Id.* at 15 (citing *WLF v. Henney*, 202 F. 3d at 337).

⁹⁵*Id.*

⁹⁶*Id.*

⁹⁷*See e.g.* FDA Warning Letter to Bristol-Meyers Squibb Co. (August 2003), *at* <http://www.fda.gov/cder/warn/2003/pravachol-wl.pdf> (April 23, 2004); FDA Untitled Letter to Cephalon, Inc. (January 2002), *at* <http://www.fda.gov/cder/warn/2002/10183.pdf> (April 23, 2004).

⁹⁸FDA Warning Letter to Bristol-Meyers Squibb Co. 6, *at* <http://www.fda.gov/cder/warn/2003/pravachol-wl.pdf>.

⁹⁹*Id.*

however, indicated an intent to take further enforcement action against the manufacturers.¹⁰⁰

Furthermore, in May 2002, FDA published a “Request for Comment on First Amendment Issues,” “seeking public comment to ensure that its regulations, guidances, policies, and practices continue to comply with the governing First Amendment case law.”¹⁰¹ FDA specifically inquired:

7. Would permitting speech by manufacturer, distributor, and marketer about off-label uses undermine the act’s requirement that new uses must be approved by the FDA? If so, how? If not, why not? What is the extent of FDA’s ability to regulate speech concerning off-label uses? And

8. Do FDA’s speech-related regulations advance the public health concerns they are designed to address? Are there other alternative approaches that FDA could pursue to accomplish those objectives with fewer restrictions on speech?¹⁰²

These two questions reflect “two different general approaches FDA might take in response to any future invalidation of its existing speech-restrictive policies governing off-label promotion” – FDA could either modify existing policies to comport with constitutional requirements or move away from the current regulatory approach and seek ‘alternative approaches’ to advance its interests.¹⁰³

FDA Regulation of Manufacturer Speech and the First Amendment

The FDA’s constitutional ability to restrain manufacturer speech about off-label uses of approved drugs is an extremely contentious topic, with the wide disparity in views well illustrated in the comments filed in

¹⁰⁰*Id.*; FDA Untitled Letter to Cephalon, Inc., at <http://www.fda.gov/cder/warn/2002/10183.pdf>.

¹⁰¹Request for Comment on First Amendment Issues, 67 Fed. Reg. 34,942 (May 16, 2002).

¹⁰³Blackwell & Beck, *supra* note 5, at 455.

response to the FDA’s “Request for Comment on First Amendment Issues.”¹⁰⁴ While a number of questions remain outstanding, some matters seem quite settled in the area of First Amendment constraints on FDA speech regulation. As one commentator has suggested, “significant First Amendment constraints on FDA speech regulation are here to stay, but . . . FDA need not worry that its ability to ensure the safety and efficacy of marketed drugs will be hamstrung by First Amendment lawsuits.”¹⁰⁵ A consensus of sorts has emerged with regards to two important issues in this area. First, after the Supreme Court’s decision in *Thompson v. Western States*, FDA will likely be unable to argue that its use of speech to prove that a manufacturer is engaging in prohibited *conduct* is not susceptible to First Amendment scrutiny.¹⁰⁶ Furthermore, as indicated by the *Washington Legal Foundation v. Friedman* court, FDA speech regulations are most likely to be regarded as commercial speech, subject to *Central Hudson* analysis.¹⁰⁷ Finally, regardless of whether manufacturer speech is in fact considered commercial in nature, “First Amendment limitations must be recognized in any effort to regulate the dissemination of off-label information” after the Supreme Court’s decision in *Western States* and the lower court decisions in *WLF*.¹⁰⁸

¹⁰⁴Richard A. Samp, *Courts Are Arriving at a Consensus on Food and Drug Administration Speech Regulation*, 58 FOOD & DRUG L.J. 313, 313 (2003).

¹⁰⁵*Id.*

¹⁰⁶Blackwell & Beck, *supra* note 5, at 445. In *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002), pharmacies challenged the FDA’s ban on advertising compounded drugs set out in 21 USC §353(a), claiming that it violated their free speech rights. The parties agreed that the advertising and soliciting prohibited by the FDAMA constituted commercial speech and that the *Central Hudson* analysis should be applied. *Id.* at 366. FDA did not attempt to claim that the prohibited advertisements were about unlawful activity or were misleading, but asserted three interests, (1) “an interest in preserving the effectiveness and integrity of the FDCA’s new drug approval process and the protection of the public health that it provides”, (2) “preserving the availability of compounded drugs for those individual patients who, for particularized medical reasons, cannot use commercially available products that have been approved by the FDA,” and (3) “achieving the proper balance between those two independently compelling but competing interests.” *Id.* at 368. The Supreme Court rejected the FDA’s contention that it was using speech restrictions as a proxy for conduct restrictions, but found preserving the effectiveness and integrity of the new drug approval process to be an important governmental interest. *Id.* at 369-71. While the Court accepted FDA’s asserted interest, and that the advertising ban might directly advance that interest, it found that FDA had failed to demonstrate that the speech restrictions were “not more extensive than is necessary to serve [those] interests.” *Id.* at 372.

¹⁰⁷*Id.* at 314. *But see* Blackwell & Beck, *supra* note 5, at 446-447, who claim that “it is likely that FDA policies restrict not only commercial speech, but also a great deal of core scientific expression regarding off-label use.”

¹⁰⁸George W. Evans & Arnold I. Friede, *The Food & Drug Administration’s Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis*, 58 FOOD & DRUG L.J. 365, 443-44 (2003).

III. Medicare and Medicaid Fraud and Abuse and the Civil False Claims Act

“Over the past decade, the health care community has witnessed dramatic changes in the government’s efforts to enforce its fraud and abuse laws.”¹⁰⁹ Health care fraud has become a major national law enforcement priority, as Americans concerned about the future of public health programs learn about the prevalence of health care fraud.¹¹⁰ “A recent audit by the Department of Health and Human Services Office of the Inspector General estimated that the Medicare program improperly paid out \$12.1 billion dollars in fiscal year 2001 alone.”¹¹¹ During the mid-1990s, then-Attorney General Janet Reno called health care fraud her, “number two new initiative, behind violent crime.”¹¹²

The Civil False Claims Act, 31 U.S.C. §§3729-3733

In this atmosphere of cracking down on health care fraud, the Civil False Claims Act (FCA) [has emerged as] the government’s “primary litigative tool for combating fraud.”¹¹³ Although the FCA is a Civil War-era statute, it has recently become the “primary weapon in the fight against health care fraud.”¹¹⁴ The FCA empowers both the Attorney General and private persons to institute civil actions to enforce the Act.¹¹⁵ The Act prohibits the knowing submission of false or fraudulent claims to the federal government and provides

¹⁰⁹HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES 112 (Linda A. Baumann, ed., ABA Health Law Section, 2002).

¹¹⁰Joan H. Krause, “Promises to Keep”: *Health Care Providers and the Civil False Claims Act*, 23 CARDOZO L. REV. 1363, 1367 (March 2002).

¹¹¹*Id.*

¹¹²Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 134 (Fall 2001).

¹¹³HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 113.

¹¹⁴Krause, *supra* note 110, at 1367.

¹¹⁵31 U.S.C. §3730 (2004).

for statutory penalties of \$5500 to \$11,000 per claim, plus treble damages.¹¹⁶ The FCA's powerful qui tam provisions allow private persons, "relators," to sue on the government's behalf, thereby increasing the likelihood of enforcement.¹¹⁷ Before 1986, the FCA was relatively unused; however, amendments in that year modernized the Act, and the government's recoveries under the FCA have skyrocketed as a result, totaling more than \$4 billion over the last decade.¹¹⁸ This proliferation of FCA suits has been accompanied by a "marked expansion in the number and types of activities targeted by the law. While the FCA initially was applied to straightforward fraudulent actions such as billing the government for health care services that were not rendered, more innovative theories of liability have recently emerged."¹¹⁹

History of the False Claims Act

The Civil False Claims Act, also known as the "Informer's Act" or "Lincoln's Law,"¹²⁰ was enacted on March 2, 1863 in response to "rampant fraud" against the Union Army during the Civil War.¹²¹ The drafters of the Act were primarily concerned with fraud on military contractors, but the Act also applied to fraud committed by all government contractors.¹²² Violators of the original FCA were subject to both civil and criminal penalties, and the 1863 Act "prohibited a wide variety of offenses against the government, including making false, fictitious, or fraudulent claims, and using false or fraudulent documentation to get claims paid."¹²³ The 1863 Act also included an unusual feature in its qui tam provisions, under which a private person could bring suit "as well for himself as for the United States" and retain half the total recovery.¹²⁴ Few decisions

¹¹⁶31 U.S.C. §3729(a) (2004); Adjustments to Penalties, 28 C.F.R. §85.3(a)(9) (2004).

¹¹⁷31 U.S.C. §3730(b)(2) (2004).

¹¹⁸HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 114.

¹¹⁹Krause, *supra* note 110, at 1367-68.

¹²⁰Joel M. Androphy & Mark A. Corroero, *Whistleblower and Federal Qui Tam Litigation – Suing the Corporation for Fraud*, 45 S.TEX. L. REV. 23, 26 (Winter 2003).

¹²¹Krause, *supra* note 110 at 1370; Act of Mar. 2, 1863, ch. 67, 12 Stat. 696 (current version at 31 U.S.C. §3729 (2004)).

¹²²Androphy & Corroero, *supra* note 120, at 26.

¹²³Krause, *supra* note 112, at 129.

¹²⁴*Id.*

were reported under the FCA before 1930, and the Act went through a number of recodifications during the period.¹²⁵

The most recent and extensive amendments to the FCA occurred in 1986 and were the result of increased concern over federal program fraud throughout the 1970s.¹²⁶ “The 1986 Amendments were designed to recast the Civil War-era statute as an effective weapon against modern forms of government fraud, particularly in defense procurement and the federal health care programs.”¹²⁷ The Amendments focused on the *qui tam* provision of the FCA, as “Congress wanted to reward private individuals who take significant personal risks by bringing wrongdoing to light, to break conspiracies of silence among employees of malfeasors, and to encourage whistleblowing and disclosure of fraud.”¹²⁸

The 1986 Amendments expanded the scope of the FCA’s scienter standard, eliminating the need to prove specific intent and making defendants liable for acting with “deliberate ignorance” or “reckless disregard” of the truth.¹²⁹ The amendments set the burden of proof on an FCA claim at “a preponderance of the evidence,”¹³⁰ and lengthened the statute of limitations from six years to a variable ten.¹³¹ Congress modernized the FCA penalty provisions, increasing the government’s recovery amounts from double to treble damages and from \$2000 per claim to \$5000 to \$10,000 per claim in civil monetary penalties.¹³² A number of amendments specifically focused on the Act’s *qui tam* provisions, one such amendment eliminated the 1943 jurisdictional bar which “precluded recovery on any violation for which the government already possessed information, and instituted a ‘public disclosure’ bar.”¹³³ Congress also included an “original source” exception to the jurisdictional bar, whereby a relator could pursue an action based on publicly disclosed in-

¹²⁵*Id.* at 130.

¹²⁶*Id.* at 132; Act of Oct. 29, 1986, §2, 100 Stat. 3153 (current version at 31 U.S.C. §3729 (2004)).

¹²⁷Krause, *supra* note 112, at 133.

¹²⁸Androphy & Carrero, *supra* note 120, at 27 (citing *United States v. Bank of Farmington*, 166 F.3d 853,858 (7th Cir. 1999)).

¹²⁹31 U.S.C. §3729(b) (2004); *Id.* at 28.

¹³⁰31 U.S.C. §3729(c) (2004); Krause, *supra* note 112, at 133.

¹³¹31 U.S.C. §3731(b)(1)-(2) (2004); Androphy & Carrero, *supra* note 120, at 28.

¹³²31 U.S.C. §3729(a) (2004). HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 114.

¹³³31 U.S.C. §3730(e)(4)(A) (2004); Androphy & Carrero, *supra* note 120, at 28.

formation if s/he could show that s/he was the initial source of the information.¹³⁴ Finally, the amendments increased the relator's award to 15-25% of the proceeds (or 25-30% if the government declined to join the suit), and expanded the relator's right to participate in the action.¹³⁵ Congress also "prohibited employers from retaliating against whistleblowers who initiate or assist in a qui tam action."¹³⁶

The 1986 Amendments have drastically increased the number of FCA claims, and specifically the number of qui tam claims filed by relators. "While only 33 qui tam cases were filed in 1987, more than 360 cases have been filed each year since 1997."¹³⁷ "The health care industry has been especially hard hit, with every sector – hospitals, fiscal agents, peer review organizations, physicians, researchers, laboratories, home health agencies, long-term care facilities, and suppliers and billing services, among others – having been the target of an FCA action."¹³⁸ Health care qui tam suits have grown dramatically relative to similar suits in other industries. In 1987, 12% of qui tam suits concerned programs regulated by the Department of Health and Human Services; by 1998, the percentage had grown to 61%.¹³⁹ It is projected that recoveries over the next decade will continue to increase – "one private group has estimated that the government, from 1996 to 2006... , will recover more than \$21 billion."¹⁴⁰

The Current Civil False Claims Act

The FCA prohibits any person from (1) knowingly presenting, or causing to be presented false or fraudulent claims for payment or approval, or (2) knowingly making, using, or causing to be made or used, false records or statements to get a false or fraudulent claim paid or approved by the government.¹⁴¹ Violators are liable

¹³⁴31 U.S.C. §3730(d)(4)(A) (2004); Krause, *supra* note 112, at 134.

¹³⁵31 U.S.C. §§3730(c)(1), 3730(d)(1)-(2) (2004); Krause, *supra* note 112, at 134.

¹³⁶31 U.S.C. §3730(h) (2004); Krause, *supra* note 112, at 134.

¹³⁷Krause, *supra* note 112, at 134.

¹³⁸HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 116.

¹³⁹Krause, *supra* note 112, at 134.

¹⁴⁰HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 116.

¹⁴¹31 U.S.C. §3729(a).

for a civil penalty of \$7500 to \$15,000 per claim, plus treble the government's damages.¹⁴² In addition to sections 3729(a)(1) and (a)(2), section 3729(a)(3) prohibits conspiracies "to defraud the Government by getting a false or fraudulent claim allowed or paid."¹⁴³ To establish an FCA violation, a plaintiff must establish a number of elements – "the plaintiff generally must prove that: (1) the 'person'; (2) 'present[ed]' or 'cause[d]' to be presented'; (3) 'a false or fraudulent'; (4) 'claim,' 'record or statement'; (5) 'knowingly'; (6) to 'the United States [government]'; that was (7) 'material' to the government's determination to pay."¹⁴⁴

The "false or fraudulent" and "knowing" elements of the FCA have produced the most litigation under the statute.¹⁴⁵ Other elements of the FCA have proven easier in application. The FCA imposes liability on persons who "present" or "cause to be presented" false or fraudulent claims.¹⁴⁶ "Cause-to-be-presented" liability applies "where the person responsible for the falsity does not actually submit the claim, but rather directs others (who may not know of the falsity) to submit the claim on his or her behalf."¹⁴⁷ This type of liability may apply to entities that offer billing advice to health care providers, and would most likely be the theory of liability used in a case based on manufacturer promotion of off-label uses.¹⁴⁸

Although the FCA does not define the term "claim," courts have interpreted it as "a demand for money or for some transfer of public property."¹⁴⁹ Under current judicial interpretation, essentially "any action by the claimant which has the purpose and effect of causing the United States to pay out money it is not obligated to pay. . . [is properly considered a 'claim'] within the meaning of the FCA."¹⁵⁰ The most controversial type

¹⁴²31 U.S.C. §3729(a)(4) provides for a penalty of \$5,000 to \$10,000 per claim, but the Medicare Prescription Drug Improvement and Modernization Act of 2003, which became effective on January 1, 2004, increased the range to between \$7,500 and \$15,000. P.L. 108-173 (Dec. 8, 2003).

¹⁴³31 U.S.C. §3729(a)(3) (2004).

¹⁴⁴HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 117-18.

¹⁴⁵*Id.* at 118.

¹⁴⁶31 U.S.C. §3729(a)(1) (2004).

¹⁴⁷Krause, *supra* note 112, at 140.

¹⁴⁸*Id.*

¹⁴⁹Pamela H. Bucy, *Growing Pains: Using the False Claims Act to Combat Health Care Fraud*, 51 ALA. L. REV. 57, 62-63 (1999).

¹⁵⁰Androphy & Carrero, *supra* note 120, at 35.

of claim in FCA litigation has been the “reverse false claim,” which involves the use of false records “to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.”¹⁵¹ The 1986 Amendments made clear that Congress intended to prohibit such claims.¹⁵²

The FCA has always included the requirement that a defendant “knowingly” present or cause to be presented false claims, however the term “knowingly” was not defined until the 1986 Amendments.¹⁵³ The FCA now defines “knowing” and “knowingly” to mean that a person: “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.”¹⁵⁴ The FCA clearly provides that “no proof of specific intent to defraud is required;”¹⁵⁵ however, mere negligence and “innocent mistakes” will not suffice to establish liability under the FCA.¹⁵⁶ The drafters of the 1986 Amendments explained these changes as serving two purposes: making it easier to prove liability under the FCA, and standardizing the mens rea requirement.¹⁵⁷ The legislative history indicates that Congress was concerned about two types of conduct that some courts had found to be not actionable prior to 1986.¹⁵⁸ First, where “a provider submitted claims in a sloppy, unsupervised fashion without due care regarding the accuracy of the claim” and second, where “a provider deliberately refused to learn additional facts that, if learned, would disclose that the claim was inaccurate.”¹⁵⁹ The 1986 clarification of “knowingly” aimed to make it more difficult for corporate officers to “insulate themselves

¹⁵¹ 31 U.S.C. §3729(a)(7) (2004).

¹⁵² Bucy, *supra* note 149, at 63.

¹⁵³ *Id.* at 60.

¹⁵⁴ 31 U.S.C. §3729(b).

¹⁵⁵ *Id.*

¹⁵⁶ Androphy & Carrero, *supra* note 120, at 36.

¹⁵⁷ S. REP. NO. 99-345, at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5272; Bucy, *supra* note 149, 61.

¹⁵⁸ HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 135 (citing 132 CONG. REC. 20, 535-36 (Aug. 11, 1986)).

¹⁵⁹ *Id.*

from knowledge of false claims submitted by lower-level subordinates.”¹⁶⁰

The terms “false” and “fraudulent” are not defined in the FCA, but “courts have held that a claim cannot be ‘false’ if submitted pursuant to a reasonable interpretation of vague statutory language.”¹⁶¹ Courts have found falsity where defendants presented health care claims or statements that were literally false, with false information reported on the claim form.¹⁶² In addition, under the “express certification” theory, courts have found that where government payment is expressly conditioned on certifying compliance with certain laws, a claimant may violate the FCA if it failed to comply with the requirement but certified that it had complied.¹⁶³ Finally, some courts have been willing to consider whether FCA claims are false by omission or “implicitly” false “because of the violation of a rule or regulation that is not specifically referenced in the claim itself.”¹⁶⁴

Theories of Liability Under the FCA

There are five traditional types of FCA cases, according to author John T. Boese – (1) the “Mischarge” case; (2) the “Fraud-in-the-Inducement” or “False Negotiation” case; (3) the “False Certification” case; (4) the “Substandard Product or Service” case; and (5) the “Reverse False Claim” case.¹⁶⁵ “Mischarge” cases involve the common element of a claim made to the government for goods and services that were not pro-

¹⁶⁰Bucy, *supra* note 149, at 61.

¹⁶¹Androphy & Carrero, *supra* note 120, at 37.

¹⁶²HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 120.

¹⁶³See e.g. United States *ex rel.* Thompson v. Columbia/HCA Healthcare, 20 F. Supp. 2d 1017, 1131 (S.D. Tex. 1998).

¹⁶⁴HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 123.

¹⁶⁵JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS §1.06, 1-39 (2d. ed. 2003).

vided in the manner set forth in the claim, either because a bill is submitted to the government for goods and services that are never delivered, or because the government is billed for a higher-price good or service than is actually provided.¹⁶⁶ In “Fraud-in-the-Inducement” or “False Negotiation” cases, false statements are made or illegal actions undertaken during the course of bidding on or negotiating federal contracts.¹⁶⁷ “False Certification” cases arise where parties either explicitly or implicitly falsely certify “statutory or regulatory compliance, or . . .¹⁶⁸ the existence (or non-existence) of certain conditions, which are alleged to be a prerequisite to the government’s payment.” When a supplier of goods or services provides an inferior substitute in place of the service or product contracted for, the case is one of “substandard product.”¹⁶⁹ Finally, as discussed above, “Reverse False Claim” cases involve situations where parties use false records to decrease or avoid a financial obligation to the government.¹⁷⁰

In all of these cases, the conduct that creates liability is some sort of fraud on the government. While the Supreme Court has stated that “the False Claims Act was not designed to reach every kind of fraud practiced on the Government,” FCA liability has been widely construed since the 1986 Amendments.¹⁷¹ Indeed, “now, with only a few exceptions, most conduct that illegally increases payment by the government of revenues to which it is entitled, has been held (correctly or not) to trigger FCA liability.”¹⁷² FCA liability most commonly arises under Subsection 3729(a)(1), discussed above, which prohibits any person from “knowingly present[ing] or caus[ing] to be presented . . . a false or fraudulent claim for payment or approval.”¹⁷³ A number of courts have held that the government need not actually pay the claim for FCA liability to arise, and courts have split over the need for damages under subsection 3729(a)(1), with some courts finding liability “even

¹⁶⁶*Id.* at §1.06[a], 1-39.

¹⁶⁷*Id.* at §1.06[B], 1-40.

¹⁶⁸*Id.* at §1.06[C], 1-41.

¹⁶⁹*Id.* at §1.06[D], 1-42.

¹⁷⁰Krause, *supra* note 110, at 1380.

¹⁷¹*United States v. McNinch*, 356 U.S. 595 (1958); BOESE, *supra* note 165, at §2, 2-5.

¹⁷²BOESE, *supra* note 165, at §2, 2-5 (citing *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 788 (4th Cir. 1999)).

¹⁷³BOESE, *supra* note 165, at §2.01[A], 2-8; 31 U.S.C. §3729(a)(1).

in the absence of a negative financial impact on the government.”¹⁷⁴ As discussed above, liability under subsection 3729(a)(1) extends not only to those who submit false claims to the government for payment but also to those who “cause” a false claim to be presented, even if they are not the actual presenters of the claim. “Cause-to-be-presented” liability is at issue in most of today’s FCA litigation, given the nature of modern business practices.¹⁷⁵ “Cause-to-be-presented” liability does not require the person submitting the claim to know that it is false, thus “a health care provider who bills Medicare through a hospital’s billing system or an outside billing service is liable if the claims are false, even though a third party innocently submits the bills.”¹⁷⁶

FCA liability under subsection 3729(a)(2) attaches where a person “knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved...”¹⁷⁷ This section can also be used to implicate defendants that did not personally submit a false claim to the government, and thus may be used in situations of “cause-to-be-presented” liability.¹⁷⁸ Violations of subsection 3729(a)(2) are more difficult to prove than violations of subsection (a)(1) because the government (or relator) must prove that the “claim” is “knowingly” false, and also “(1) that the record supporting the claim is false and (2) that the record is made or used for the purpose of causing the false claim to be paid.”¹⁷⁹

The Qui Tam Provision of the FCA

In addition to providing for actions by the government to enforce the FCA, the FCA allows private persons,

¹⁷⁴BOESE, *supra* note 165, at §2.01[A], 2-9.

¹⁷⁵*Id.* at 2-10.

¹⁷⁶*Id.* at 2-11 (citing *United States ex rel. Franklin v. Parke-Davis*, 147 F.Supp. 2d at 39).

¹⁷⁷31 U.S.C. §3729(a)(2).

¹⁷⁸BOESE, *supra* note 165, at §2.01[B], 2-22.

¹⁷⁹*Id.* at 2-23-24.

known as relators, to act as “private attorneys general” in bringing suit under the Act’s qui tam provisions.¹⁸⁰ The rationale for the qui tam provision, as expressed in 1986, is that “in the face of sophisticated and widespread fraud... only a coordinated effort of both the Government and the citizenry will decrease th[e] wave of defrauding public funds.”¹⁸¹ Despite statutory caps on relators’ recoveries, qui tam suits may allow significant recoveries; the average relators’ recovery is one million dollars, but some recent recoveries include \$42 million to relators on a \$333,976 million settlement, \$2.34 million to relators on a \$12.65 million recovery, and \$2.4 million to relators on a \$10 million recovery.¹⁸²

The qui tam provisions include elaborate procedures that relators must follow in bringing suits under the FCA.¹⁸³ The relator is required to serve the complaint on the government along with written disclosure of substantially all material evidence and information the relator possesses regarding the complaint.¹⁸⁴ The complaint is filed in camera and remains under seal for at least 60 days, during which time the government investigates the allegations and decides whether or not to formally intervene.¹⁸⁵ After investigating, if the government decides the allegations have merit, the Department of Justice intervenes in the action, unseals the complaint, and assumes primary responsibility for prosecuting the case.¹⁸⁶ The government may then move to settle or dismiss the case over the objections of the relator.¹⁸⁷ If the government believes the claim lacks merit and declines to intervene, it notifies the court of its decision, and the relator has the right to prosecute the action, but is not obligated to do so.¹⁸⁸

The success of a qui tam action, as well as the relator’s right to recovery may turn on whether the government decides to intervene or not. If the government intervenes and prevails on the merits, it is entitled to recover treble damages plus \$7,500 to \$15,000 for each false claim submitted.¹⁸⁹ In this case, the relator usually

¹⁸⁰31 U.S.C. §3730(b)(2); Bucy, *supra* note 149, at 87.

¹⁸¹S. REP. NO. 99-345, at 7; Bucy, *supra* note 149, at 87.

¹⁸²*Id.*

¹⁸⁹Medicare Prescription Drug Improvement and Modernization Act of 2003, P.L. 108-173.

receives 15 to 25% of the government’s recovery plus reimbursement of reasonable legal fees and expenses.¹⁹⁰ If the government does not intervene in the action, the relator can recover between 25 and 30% of the government’s recovery, plus reimbursement of reasonable legal fees and expenses.¹⁹¹ Where the government declines to intervene in qui tam cases, FCA actions generally do not result in any governmental recovery.¹⁹² As of November 1999, the DOJ intervened in approximately 21 percent of all qui tam cases, and recovered \$2.9 billion in those cases. The 79 percent of qui tam cases in which the government did not intervene, however, only amounted to \$410 million in recovery (13 percent of the government’s total recoveries).¹⁹³

The FCA places three significant limitations on relators’ ability to bring qui tam suits in the form of jurisdictional bars that prevent courts from hearing certain types of actions. Subsection 3730(e)(4) prohibits qui tam actions based on information that has already been publicly disclosed unless the relator is the government’s original source of the information.¹⁹⁴ Subsection 3730(e)(3) of the FCA prohibits qui tam actions based upon allegations or transactions that are the subject of a civil or administrative suit to which the government is already a party.¹⁹⁵ Subsection 3730(b)(5) prohibits all actions based on facts underlying a pending action.¹⁹⁶ These three jurisdictional bars compel various “races”— subsection 3730(e)(4) requires relators to report fraud before it is publicized, subsection 3730(e)(3) forces relators to race the government to the courthouse, and subsection 3730(b)(5) has relators racing each other to the court house.¹⁹⁷ Each of these provisions aim “to compel whistleblowers to disclose perceived wrongdoing to the government at the

¹⁹⁰31 U.S.C. §§3729(a) and 3730(d)(1). The relator’s right to recovery depends on his/her contribution to the action; also, under §3730(d)(1), the relator’s recovery may be capped at 20% if it is based on certain types of information.

¹⁹¹31 U.S.C. §3730(d).

¹⁹²HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 149.

¹⁹³*Id.* at 149-50 (citing Qui Tam Statistics *available at* <http://www.taf.org>).

¹⁹⁴31 U.S.C. §3730(e)(4).

¹⁹⁵31 U.S.C. §3730(e)(3).

¹⁹⁶31 U.S.C. §3730(b)(5).

¹⁹⁷HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 153.

earliest possible moment.”¹⁹⁸

The jurisdictional bar that has resulted in the most litigation and the dismissal of a substantial number of actions is the public disclosure jurisdictional bar.¹⁹⁹ The public disclosure jurisdictional bar was not included in the original FCA enacted in 1863, but was added to the statute in 1943, “after a series of abuses in which private persons filed qui tam actions based expressly on public information.”²⁰⁰ Most strikingly, in the Supreme Court case *United States ex rel. Marcus v. Hess*, a relator used information from a publicly filed indictment, which had already resulted in a conviction, to file a qui tam action.²⁰¹ The Court noted that strong policy arguments advised against the statutory plan, but that those arguments were properly directed to Congress as the current statute allowed qui tam relators to file based on public information.²⁰² Congress reacted by including the public disclosure jurisdictional bar provision, which aimed to prevent “parasitic suits,” providing that no action could be filed based on information in the government’s possession, even if the relator was the original source of the information.²⁰³

Congress reconsidered the public disclosure jurisdictional bar in passing the 1986 Amendments, this time spurred to action by a Seventh Circuit case. In *United States ex rel. Wisconsin v. Dean*, the state of Wisconsin successfully prosecuted Alice R. Dean, M.D. under its criminal statutes for submitting fraudulent claims under Medicaid.²⁰⁴ Wisconsin then reported the conviction to the federal government, as required by the Medicaid program and proceeded to file a qui tam suit as relator to recover from Dean damages resulting from the fraudulent claims.²⁰⁵ The Seventh Circuit found itself forced to dismiss the suit because it was based upon evidence in possession of the United States at the time the complaint was filed, and thus

¹⁹⁸*Id.*

¹⁹⁹*Id.* at 150.

²⁰⁰*Id.* at 151.

²⁰¹*United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943).

²⁰²*Id.* at 540; Bucy, *supra* note 149, at 90.

²⁰³HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 151.

²⁰⁴*United States ex rel. Wisconsin v. Dean*, 729 F.2d 1100 (7th Cir. 1984).

²⁰⁵*Id.* at 1102.

subject to the jurisdictional bar in place at the time, despite the fact that the state of Wisconsin was the original source of the information at issue in the suit.²⁰⁶ Congress reacted by altering the public disclosure jurisdictional bar so as to allow actions based on public information if the whistleblower was the “original source” of the publicly disclosed information.²⁰⁷ The current public disclosure jurisdictional bar prevents a court from considering:

an action...based upon the disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.²⁰⁸

Qui tam suits are ordinarily allowed under the FCA because when information is not in the public domain the government may not be aware of the information and is thus unable to act on it in the public interest; qui tam suits therefore increase the government’s access to relevant information.²⁰⁹ When information is publicly known, however, qui tam suits are barred unless the relator was the government’s original source of the information.²¹⁰ The rationale behind this policy is that once allegations of fraud have been publicly disclosed, the whistleblower’s action will not advance the public interest because the government is aware of the information and may pursue the action. Thus, a qui tam suit based on publicly disclosed information may in fact hinder the public interest because the government is compelled to share a portion of its recovery with the relator, who has done nothing more than republish public allegations.²¹¹ The public disclosure jurisdictional bar is therefore meant to ensure that “qui tam actions [will] augment the government’s recoveries in FCA actions and, at the same time, eliminate qui tam actions when such actions [are] not needed to protect the

²⁰⁶*Id.* at 1104.

²⁰⁷HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 151.

²⁰⁹HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 152.

²¹⁰31 U.S.C. §3730(e)(4)(A).

²¹¹HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 152.

federal fisc.”²¹²

While the public disclosure jurisdictional bar clearly has laudable aims, it has engendered a great deal of litigation over the various issues involved in its application. “In order to invoke the public disclosure jurisdictional bar successfully, [a] defendant must establish. . . : (1) that there has been a ‘public disclosure,’ (2) of ‘allegations or transactions,’ (3) in a ‘criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media,’ and (4) that the relator’s action is ‘based upon’ that public disclosure.”²¹³ The three most difficult questions to resolve in applying the public disclosure jurisdictional bar are: “whether the allegations in the FCA action have been previously disclosed publicly, (2) whether the lawsuit is ‘based upon’ the publicly disclosed information, and (3) whether the qui tam relator is an ‘original source’ of the information.”²¹⁴ These three questions have given rise to a significant body of case law construing the public disclosure jurisdictional bar.²¹⁵

Medicare and Medicaid Reimbursement of Prescription Drugs

The Medicare and Medicaid programs each provide for limited prescription drug benefits for beneficiaries. Generally, individuals who are 65 and are entitled to Social Security or Railroad Retirement benefits are automatically entitled to and enrolled in Medicare Part A (which typically covers inpatient hospital services)

²¹²*Id.* (citing *Findley v. FPC-Boron Employees’ Club*, 105 F.3d 675, 680-81 (D.C. Cir. 1997).

²¹³*Id.* at 155.

²¹⁴Bucy, *supra* note 149, at 88.

²¹⁵*Id.*; HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 155.

and will be deemed to have also enrolled in Medicare Part B (which typically covers outpatient health care expenses, including doctors fees).²¹⁶ Medicaid is only available to “certain low-income individuals and families who fit into an eligibility group that is recognized by federal and state law.”²¹⁷ Medicaid is administered by individual states, each of which (1) establishes its own eligibility standards, (2) determines the type, amount, duration, and scope of services, (3) sets the rate of payment for services, and (4) administers its own program.²¹⁸

The prescription drug benefits available to beneficiaries vary by program. The Original Medicare Program generally does not cover prescription drugs, but supplemental insurance plans (Medigap plans) and Medicare+Choice plans (currently also known as MedicareHMOs, will officially be called Medicare Advantage as of 2004) may allow prescription drug coverage to Medicare beneficiaries. The specific prescription drug benefits available under Medigap plans are tied to the definition of “outpatient prescription drugs,” while the specific prescription drug benefits available under Medicare+Choice plans are determined by the individual private insurer’s formulary.²¹⁹ Medicare will begin covering prescription drugs in 2006, under the Medicare Prescription Drug Improvement and Modernization Act of 2003.²²⁰ Medicaid makes prescription drug coverage an optional service, which states may receive matching federal funding to provide.²²¹ All states currently provide prescription drug coverage under Medicaid, subject to a number of strict limitations.²²²

Medicare, Medigap, and Medicare+Choice Prescription Drug Benefits

²¹⁶Social Security Act §406, 42 U.S.C. §1395p(f) (2004).

²¹⁷Centers for Medicare and Medicaid Services, *What Is Medicaid?*, at <http://www.cms.hhs.gov/medicaid/whatismedicaid.asp>, (March 18, 2004).

²¹⁸Centers for Medicare and Medicaid Services, *Medicaid: A Brief Summary*, at <http://www.cms.hhs.gov/publications/overview-medicare-medicaid/default4.asp>, (March 18, 2004).

²¹⁹Debra A. Draper et al., *How do M+C Plans Manage Pharmacy Benefits? Implications for Medicare Reform* 12, Kaiser Family Foundation (March 2003), <http://www.kff.org>, (March 19, 2004).

²²⁰Medicare Prescription Drug Improvement and Modernization Act of 2003, P.L. 108-173.

²²¹*Medicaid: A Brief Summary*, at <http://www.cms.hhs.gov/publications/overview-medicare-medicaid/default4.asp>.

²²²HARVEY L. MCCORMICK, *MEDICARE AND MEDICAID CLAIMS AND PROCEDURES*, §23.102, 210 (3d. ed. 2001).

The Medicare program currently does not cover most outpatient prescription drugs, so Medicare beneficiaries must pay 100% of their prescription drug costs unless they are covered by a supplemental plan.²²³ Through the Medicare Part B program, Medicare will cover a very limited number of outpatient prescription drugs, mostly cancer drugs.²²⁴ Medicare Part B requires beneficiaries to pay a monthly premium, and beneficiaries must still pay 20% of the costs of the limited outpatient drugs that Medicare covers.²²⁵

In addition to basic Medicare benefits, beneficiaries may have some prescription drug coverage under either a Medigap insurance plan or a Medicare+Choice plan. As of the Fall of 1999, 7% of non-institutionalized Medicare beneficiaries had prescription drug coverage under Medigap plans, and 15% had prescription drug coverage through Medicare+Choice plans.²²⁶ Medigap plans are sold by private insurance companies to “bridge the gap” between what the Original Medicare Plan pays and the balance of the beneficiary’s medical bills.²²⁷ Federal law requires insurers to sell Medigap policies that are one of ten standard supplemental plans created by the Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration (HCFA)) in all states but Minnesota, Massachusetts, and Wisconsin.²²⁸ Only two of the ten standard supplemental plans provide a basic prescription drug benefit, and one of the standard supplemental plans provides an extended prescription drug benefit.²²⁹

²²³ *Your Medicare Coverage*, (accessed for Massachusetts and Florida), at <http://www.medicare.gov>, (March 18, 2004). According to the Kaiser Family Foundation website, “Prescription drug use increases with age along with the prevalence of chronic and acute health problems. However, because Medicare does not cover outpatient prescription drugs, 38% of seniors and younger beneficiaries with disabilities had no drug coverage in the Fall of 1999.” Kaiser Family Foundation, *Prescription Drugs: Medicare*, at <http://www.kff.org/rxdrugs/medicare.cfm>, (March 19, 2004).

²²⁴ *Your Medicare Coverage*, at <http://www.medicare.gov>. In order for Medicare to cover any prescription drugs, a pharmacy or doctor must accept assignment on the drugs. Covered drugs include: some antigens, osteoporosis drugs, erythropoietin (for end-stage renal disease), hemophilia clotting factors, injectable drugs, immunosuppressive drugs, some oral cancer drugs, and oral anti-nausea drugs for people getting Medicare-covered oral anti-cancer drugs.

²²⁵ *Id.*

²²⁶ Kaiser Family Foundation, *Medicare and Prescription Drugs Fact Sheet* 1, April 2003, <http://www.kff.org>, (March 19, 2004).

²²⁷ 2003 MEDICARE HANDBOOK, §8.01, 8-3 (Judith A. Stein and Alfred J. Chiplin, Jr, eds., 2003); *Medigap Policy Basics*, at <http://www.medicare.gov/medigap/default.asp>, (March 18, 2004).

²²⁸ 2003 MEDICARE HANDBOOK, *id.* at §8.02, 8-3, §8.03, 8-4.

²²⁹ *Id.* at §8.03, 8-5. The basic benefit has a \$250 annual deductible, and covers 50% of prescription drug costs, with a maximum benefit of \$1,250 annually. The extended benefit also has a \$250 annual deductible and covers 50% of prescription drug costs, but has a maximum benefit of \$3,000 annually.

As of April 2003, 11% of Medicare beneficiaries were enrolled in Medicare+Choice plans, however, the share of Medicare+Choice enrollees in basic plans with drug coverage declined from 84% in 1999 to 69% in 2003.²³⁰ Medicare+Choice plans are offered by private companies that contract with the Medicare program to offer Medicare Health Plans.²³¹ Specific prescription drug coverage under Medicare+Choice plans varies by the private insurer and coverage is usually based on the individual insurer's formulary, a list of drugs that the plan encourages physicians to prescribe for enrollees.²³² Through their formulary structures, Medicare+Choice plans steer beneficiaries toward cost effective drug alternatives, when available.²³³ Medicare+Choice plans typically use the same formulary as they do for their commercial insurance plans, with some exceptions.²³⁴ Formularies may be open, where all drugs are covered in the formulary, but beneficiaries are encouraged to choose certain drugs through the copayment structure, or closed, where off-formulary drugs are not covered (although medical exceptions may be made for drugs that are medically necessary through an approval process).²³⁵

As of 2000, 33 states had passed legislation authorizing the use of formularies by Managed Care Organizations (MCOs).²³⁶ Fifteen states required access to non-formulary drugs if (1) they are medically necessary, (2) they are prescribed by a physician, and (3) the preferred drug is ineffective or reasonably expected to cause an adverse or harmful reaction.²³⁷ In addition, fifteen states required MCOs to provide coverage when scientific results reported in the medical literature support the off-label use of a drug for a medical condition.²³⁸ "An

²³⁰Kaiser Family Foundation, *Medicare+Choice Fact Sheet* 1-2 (April 2003), <http://www.kff.org>, (March 19, 2004).

²³¹*Medicare Plan Choices*, at <http://www.medicare.gov/Choices/Overview.asp>, (March 18, 2004).

²³²*Medicare Personal Plan Finder*, at <http://www.medicare.gov>, (March 18, 2004); *How do M+C Plans Manage Pharmacy Benefits? Implications for Medicare Reform* at 12, <http://www.kff.org>.

²³³*Id.* at 11.

²³⁴*Id.* at 12.

²³⁵*Id.*

²³⁶DESCRIPTION AND ANALYSIS OF THE VA NATIONAL FORMULARY, Ch. 5 "How Does the VA National Formulary Compare with Private Insurance Formularies for Drugs and Devices and with Other Government Formularies?" 153 (David Blumenthal and Roger Herdman eds. 2000), <http://books.nap.edu/openbook/0309069866/html/149.html>, (March 12, 2004).

²³⁷*Id.*

²³⁸*Id.*

additional 15 states specifically require[d] off-label coverage for the treatment of cancer.”²³⁹

Under the Medicare Prescription Drug Improvement and Modernization Act of 2003, Medicare will begin to cover some degree of prescription drugs in 2006.²⁴⁰ All Medicare beneficiaries will be able to enroll in a plan that will cover prescription drugs. Individual plans may vary, but generally: (1) beneficiaries will choose a plan and pay a premium of \$35 per month, (2) beneficiaries will pay a \$250 deductible, (3) Medicare will pay 75% of costs between \$250 and \$2,250 in drug spending, the beneficiary will pay the other 25% of the costs, (4) the beneficiary will pay 100% of drug costs above \$2,250 until s/he reaches \$3,600 in out-of-pocket spending, and (5) Medicare will pay about 95% of costs after the beneficiary has spent \$3,600.²⁴¹ Extra help will be available for people with low incomes and limited assets.²⁴² No new Medigap plans with prescription drug coverage will be sold after 2006, beneficiaries with Medigap policies with prescription drug coverage may choose to renew their policies, but if they join a Medicare prescription drug plan, they will not be able to renew their Medigap policy.²⁴³

Medigap and Medicare+Choice both currently offer prescription drug coverage to Medicare beneficiaries, and Medicare will begin offering more extensive prescription drug coverage in 2006 (Part D plans), all of which are or will be offered through partnerships with private insurance companies that meet the eligibility requirements for participating in the programs and enter into contracts with the Secretary of HHS.²⁴⁴ When privately insured beneficiaries submit claims for drug coverage, such claims cannot by definition, constitute false claims under the FCA, as they are not submitted to the government for payment. However, Medigap, Medicare+Choice, and Medicare Part D plans are or will be provided through contracts between private insurers and the Secretary of HHS. These contracts provide for risk sharing arrangements with the federal

²³⁹*Id.*

²⁴⁰P.L. 108-173.

²⁴¹*The Facts about Upcoming New Benefits in Medicare*, at <http://www.medicare.gov/Publications/Pubs/pdf/11054.pdf>, (March 18, 2004).

²⁴²*Id.*

²⁴³*Frequently Asked Questions*, at <http://www.medicare.gov/MedicareReform/>, (March 18, 2004).

²⁴⁴Kaiser Family Foundation, *Prescription Drug Coverage for Medicare Beneficiaries: An Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003* 7 (January 2004), <http://www.kff.org>, (March 19, 2004).

government which create federal financial involvement, and may thus create the potential for false claims under the FCA if claims submitted ought not be paid under the Medicare laws.²⁴⁵

The degree of federal financial involvement in these plans varies in amount and in complexity. Medicare uses monthly per person county rates to determine payments to Medicare+Choice plan participants.²⁴⁶ Part D plans will receive government reinsurance payments of 80% of allowable drug costs over the annual out-of-pocket payment thresholds for an enrollee.²⁴⁷ “Allowable drug costs” means drug benefit costs actually paid by the plan or the enrollee.²⁴⁸ In addition, Part D plan contracts provide for risk corridors, which limit the insurer’s risk of losing money but also limit its profits by creating a target cost for a benefit.²⁴⁹ Gains or losses inside the risk corridor around that target are borne by the private insurer, but additional gains and losses outside the risk corridor are borne by the federal government.²⁵⁰ These two risk sharing mechanisms implicate the federal treasury substantially in the prescription drug benefit claims submitted by beneficiaries under Medicare Part D plans and may therefore create the potential for false claims under the FCA (discussed below).

Medicaid Prescription Drug Benefits

The relationship between Medicaid and false claims under the FCA is much more straightforward, as Medicaid costs are paid by the states, with matching funds from the federal government. Thus claims for prescription drugs that should not be covered under the Medicaid laws are more clearly false claims under the FCA. Medicaid currently allows for the coverage of prescription drugs, subject to strict limitations.²⁵¹ Medicaid

²⁴⁵*Id.* at 7, <http://www.kff.org>.

²⁴⁶Centers for Medicare and Medicaid Services, *Federal Payment Methodology to Medicare Health Plans Fact Sheet*, at <http://www.cms.hhs.gov/media/press/release.asp?Counter=978>, (March 19, 2004).

²⁴⁷*Prescription Drug Coverage for Medicare Beneficiaries* at 3, <http://www.kff.org>.

²⁴⁸*Id.*

²⁴⁹*Id.* at 16.

²⁵⁰*Id.*

²⁵¹MCCORMICK, *supra* note 222, at §23.102, 210.

prescription drug benefits are administered through individual states' Medical Assistance Programs under Title XIX of the Social Security Act and applicable state laws.²⁵² Outpatient prescription drugs are one of the variety of optional services eligible for federal matching funds under Title XIX of the SSA, and every state's Medicaid program provides coverage for prescription drugs.²⁵³ The current Medicaid prescription drug benefit is governed by provisions enacted in the Omnibus Budget Reconciliation Acts of 1990 and 1993 (OBRA 1990, 1993), as well as Title XIX of the SSA.²⁵⁴

In order to receive federal matching funds for payment for covered outpatient drugs in any state, the manufacturer must enter into a rebate agreement with HHS and the state must provide for drug use review.²⁵⁵ "Standardization of state formularies and prior approval systems is required. Medicaid now covers products of manufacturers that have signed rebate agreements (as essentially all do) and may only exclude products in accordance with specific federal regulation."²⁵⁶ "In general, when states elect to cover outpatient prescription drugs through Medicaid, they must cover all Food and Drug Administration (FDA)-approved pharmaceuticals of every manufacturer that has signed a federal drug rebate agreement with the Secretary of Health and Human Services."²⁵⁷ The rebate agreements require that the best price a manufacturer gives to any other purchaser, including any cash or volume discount rebate, is automatically given to every Medicaid program.²⁵⁸ Within that framework, states have leeway to design and manage their prescription drug benefits, and many states aggressively manage their prescription drug benefits in order to control costs.²⁵⁹

²⁵²DESCRIPTION AND ANALYSIS OF THE VA NATIONAL FORMULARY, *supra* note 236, at 155, <http://books.nap.edu/openbook/0309069866/html/149.html>.

²⁵³DESCRIPTION AND ANALYSIS OF THE VA NATIONAL FORMULARY, *supra* note 236, at 156-57, <http://books.nap.edu/openbook/0309069866/html/149.html>.

²⁵⁴*Id.* at 157; 42 U.S.C. §1396r-8 (2004).

²⁵⁵42 U.S.C. §1396r-8(a), (g). MCCORMICK, *supra* note 222, at §23.102, 210.

²⁵⁶DESCRIPTION AND ANALYSIS OF THE VA NATIONAL FORMULARY, *supra* note 236, at 158, <http://books.nap.edu/openbook/0309069866/html/149.html>.

²⁵⁷Kaiser Commission on Medicaid and the Uninsured, *Medicaid Outpatient Prescription Drug Benefits: Findings From a National Survey, 2003* i (December 2003), <http://www.kff.org>, (March 19, 2004).

²⁵⁸DESCRIPTION AND ANALYSIS OF THE VA NATIONAL FORMULARY, *supra* note 236, at 158, <http://books.nap.edu/openbook/0309069866/html/149.html>.

²⁵⁹*Medicaid Outpatient Prescription Drug Benefits* at i, iii, <http://www.kff.org>. Some common mechanisms for managing the

As noted above, states must cover FDA-approved products of manufacturers that have signed federal drug rebate agreements with the Secretary of HHS. The caveat that products must be FDA-approved comes from the restriction in the Social Security Act that defines “covered outpatient drug” by stating “the term ‘covered outpatient drug’ does not include any drug . . . used for a medical indication which is not a medically accepted indication.”²⁶⁰ A “medically accepted indication” is defined as “any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by” one of specified compendia.²⁶¹ There is a narrow exception that allows for payment for certain drugs that are not otherwise covered where the drugs have been determined to be “essential to the health of the beneficiaries.”²⁶²

IV.

FCA Liability for Manufacturer Promotion of Off-Label Uses?

United States ex rel. Franklin v. Parke-Davis

On August 13, 1996, David Franklin, as relator, filed a nine-count qui tam action in *United States ex rel.*

prescription drug benefit include: prior authorization of at least some prescription drugs; fail-first/step therapy (a particular drug is not dispensed unless it has been determined that another drug has been tried and is inappropriate for the patient); excluded drugs (Medicaid laws allow states to exclude certain categories of drugs from coverage, e.g. drugs with high potential for abuse or drugs used for cosmetic purposes); preferred drug lists (PDLs); supplemental rebates; generics; quantity limits; and cost-sharing.

²⁶⁰42 U.S.C. §1396r-8(k)(3).

²⁶¹42 U.S.C. §1396r-8(k)(6), *see also* 42 U.S.C. §1396r-8(g)(1)(B)(i) for specified compendia, including American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, and the DRUGDEX Information System.

²⁶²42 U.S.C. §1396r-8(a)(3).

Franklin v. Parke-Davis.²⁶³ Franklin (also “Relator”) holds a doctorate in biology, is accomplished in the medical field, and was employed by the defendant pharmaceutical manufacturer, Parke-Davis, as a “medical liaison” for five months during 1996.²⁶⁴ Franklin alleged that Parke-Davis “engaged in an extensive and far-reaching campaign to use false statements to promote increased prescriptions of Neurontin and Accupril for off-label uses which caused the filing of false claims for reimbursement by the federal government.”²⁶⁵ Neurontin was approved by the FDA in 1994 for use as an adjunctive treatment for epilepsy.²⁶⁶ It is also used for a number of off-label purposes, including pain control, as mono-therapy for epilepsy, for control of bipolar disease, and as treatment for attention deficit disorder.²⁶⁷ Franklin claimed that 50% of Neurontin’s sales in 1996 were attributable to off-label uses and that, of those sales, 50% “were reimbursed by the government either indirectly through Medicaid or directly through purchases by the Veterans Administration.”²⁶⁸ Accupril is an ACE inhibitor that has been by the FDA for control of hypertension and as a treatment for heart failure.²⁶⁹

Franklin alleged that he was hired by Parke-Davis as a “medical liaison” and was “instructed to make exaggerated or false claims concerning the safety and efficacy of Parke-Davis drugs for off-label uses.”²⁷⁰ In addition, Franklin claimed that he was trained to represent that Neurontin could be prescribed for its various off-label uses in amounts of up to 4800 mg per day although the drug was only FDA-approved for a maximum dosage of 1800 mg per day.²⁷¹ Franklin furthermore claimed that medical liaisons were “encouraged to misrepresent their scientific credentials and to pose as research personnel rather than as sales representatives,”

²⁶³United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d at 46.

²⁶⁴*Id.* at 44. Franklin “has co-authored five scientific publications, is an author of a pending patent application, and received a two-year research fellowship with Harvard Medical School and the Dana Farber Cancer Institute in Boston in 1992.” *Id.* At the time the relator filed the complaint, Parke-Davis was a division of Warner-Lambert Company; Warner-Lambert was subsequently acquired by Pfizer, Inc. in June 2000. *Id.* at n.2.

²⁶⁵*Id.* at 45.

²⁶⁶*Id.*

²⁶⁷*Id.*

²⁶⁸*Id.*

²⁶⁹*Id.*

²⁷⁰*Id.*

²⁷¹*Id.*

despite the fact that medical liaisons had no connection to Parke-Davis' research division.²⁷² According to Franklin, when questions were raised regarding the availability of reimbursement for off-label prescriptions of Parke-Davis drugs, medical liaisons "were instructed to coach doctors on how to conceal the off-label nature of the prescription."²⁷³ Franklin claimed that Parke-Davis shredded documents, falsified documents, and encouraged medical liaisons not to leave a "paper trail" that could be followed by the FDA, in order to conceal its promotion of off-label uses for its drugs from the FDA.²⁷⁴

In addition, Franklin made claims relating to potential violations of the Medicaid Antikickback Provision. He alleged that doctors were rewarded with various forms of compensation for prescribing large quantities of Parke-Davis drugs.²⁷⁵ These kickbacks included various monetary payments disguised as compensation for other things such as drug studies which had no scientific value and physicians' services as "consultants" or "preceptors" or for participating in a "speakers bureau."²⁷⁶ Physicians also reportedly received "cash payments for small record-keeping tasks, such as allowing Parke-Davis access to information about the doctors' patients who were receiving Neurontin."²⁷⁷ Finally, Franklin alleged that doctors who prescribed "large amounts of Parke-Davis drugs were given gifts such as travel and tickets to the Olympics."²⁷⁸

After Franklin filed his complaint, the case remained under seal for several years while the government contemplated intervening.²⁷⁹ To date, the government is participating only as an "amicus curiae while

²⁷² *Id.*

²⁷³ *Id.* at 46.

²⁷⁴ *Id.*

²⁷⁵ *Id.*

²⁷⁶ *Id.*

²⁷⁷ *Id.*

²⁷⁸ *Id.*

²⁷⁹ *Id.*

reserving its right to intervene as plaintiff at a later point,” and has filed a Statement of Interest.²⁸⁰ The seal on the complaint was lifted on December 21, 1999, at which point litigation on the case began.²⁸¹

Motion to Dismiss Decision

Parke-Davis moved for dismissal of Franklin’s qui tam allegations, claiming he had failed to plead a claim of fraud with particularity pursuant to Fed. R. Civ. P. 9(b) and failed to state a claim upon which relief could be granted pursuant to Fed. R. Civ. P. 12(b)(6).²⁸² The federal district court for the District of Massachusetts issued its opinion on the motion to dismiss on June 25, 2001, granting the motion in part and denying the motion in part.²⁸³ The court noted that qui tam actions under the FCA must comply with Fed. R. Civ. P. 9(b)’s requirement that “the circumstances constituting fraud...shall be stated with particularity,” and found that Franklin had not sufficiently pled fraud with particularity as to Parke-Davis’ promotion of off-label uses of Neurontin in direct sales to the Veterans’ Administration, nor as to Parke-Davis’ promotion of off-label sales of Accupril.²⁸⁴ The court thus dismissed those claims, and also dismissed Franklin’s claims of violations of the Medicaid Antikickback provision as well as further claims that Parke-Davis “engaged doctors to perform clinical trials using Parke-Davis drugs in violations of FDA regulations requiring that the drugs for such trials be provided at no cost.”²⁸⁵

However, the court found that Franklin had sufficiently pleaded fraud with particularity and stated a claim upon which relief could be granted in alleging Parke-Davis’ promotion of off-label uses of Neurontin for Medicaid reimbursement and the resulting FCA claims.²⁸⁶ As to the motion to dismiss for failure to plead fraud with particularity, the court stated that:

²⁸⁰ *Id.*; United States *ex rel.* Franklin v. Parke-Davis, No. 96-11651, U.S. Dist. LEXIS 15754, at *1 (D.Mass. Aug. 22, 2003).

²⁸¹ *Id.*

²⁸² *Id.* at 43-44.

²⁸³ *Id.* at 44.

²⁸⁴ *Id.* at 46, 49-50.

²⁸⁵ *Id.* at 55.

²⁸⁶ *Id.* at 49, 53.

although Relator’s complaint alleges a general framework of what might be actionable FCA claims, those allegations standing alone lack the specificity required under Rule 9(b). The complaint does not disclose the “who, what, when, where, and how” of the alleged fraud.²⁸⁷

The court found it appropriate, however, to look to the Franklin’s disclosure to the government pursuant to section 3730(b)(2) of the FCA, because the disclosure was referenced in the complaint.²⁸⁸ Taking the disclosure into consideration, the court found that Franklin’s complaint contained allegations of fraud sufficient to satisfy Rule 9(b).²⁸⁹ The disclosure described a scheme designed to increase the submission of off-label prescriptions for Neurontin, including false statements made to physicians to induce off-label prescriptions for Neurontin, identifying individuals at Parke-Davis involved in the scheme and the physicians contacted by name.²⁹⁰ The disclosure also described a “fraudulent marketing campaign conducted by Parke-Davis in which. . . unlawful and misleading marketing [was] allegedly used to encourage doctors to increase their use of Neurontin for unapproved purposes.”²⁹¹ In the disclosure, Franklin cited at least eleven specific examples of fraudulent statements that medical liaisons were trained to and did give to physicians to induce the purchase of Neurontin for off-label uses.²⁹² These false statements included:

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Franklin himself “deliberately contrived reports to mislead physicians into believing that a body of data existed that demonstrated the effectiveness of Neurontin in the treatment of bipolar disease,” although no data in fact existed to support this use;²⁹³

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Franklin was trained and instructed to use falsified “leaks” from clinical trials, scientifically flawed reports, or success stories stating that Neurontin was highly effective in treating a variety of pain syndromes, although no such body of evidence of existed;²⁹⁴

²⁸⁸ *Id.*

²⁸⁹ *Id.* at 48.

²⁹⁰ *Id.*

²⁹¹ *Id.*

²⁹² *Id.*

•

Franklin was instructed to advise physicians that Parke-Davis had developed a large body of data to support the use of Neurontin as mono-therapy although this was an “outright lie” and left patients unknowingly without good seizure control;²⁹⁵

•

Medical liaisons were instructed to tell physicians a great deal of data existed that supported the safe use of Neurontin at levels exceeding 4800 mg per day although clinically significant safety data only existed at dosing levels of 1800 mg per day; and ²⁹⁶

•

Parke-Davis provided medical liaisons with slides stating that Neurontin was effective in treating Attention Deficit Disorders although no data existed to support the claim;²⁹⁷

The district court thus found that the allegations in the complaint and disclosure sufficiently pled fraud with particularity, and that Franklin did not have to identify each false claim, as the defendant argued, given the complexity and scope of the alleged scheme of fraud.²⁹⁸ The court found that this expectation would be unreasonable as Franklin did not have pre-discovery access to the patient-specific information required to plead fraud with such specificity.²⁹⁹

In addition to finding that Franklin sufficiently pled fraud with particularity as to Parke-Davis’ promotion of Neurontin for off-label uses, the district court also determined that although Franklin’s complaint “takes the parties into territory that is not well charted by the existing decisional law,” it sufficiently stated a claim upon which relief could be granted and should thus survive Parke-Davis’ motion to dismiss under Fed. R. Civ. P. 12(b)(6).³⁰⁰ The court set forth the requirements for bringing an FCA action – “(1)... a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due...” and noted

²⁹⁸ *Id.*

²⁹⁹ *Id.*

³⁰⁰ *Id.* at 53.

that the Supreme Court has indicated that the “False Claims Act is intended to reach all types of fraud, without qualification, that might result in financial loss to the Government.”³⁰¹ Parke-Davis did not dispute that off-label prescriptions submitted for Medicaid reimbursement are false claims within the meaning of the FCA, but rather attacked “the viability of a claim under the FCA against a manufacturer that did not itself submit false claims in the form of off-label prescriptions directly to the government.”³⁰² The court therefore focused on the four elements of Parke-Davis’ attack on Franklin’s theory of FCA liability, rejecting each argument in turn.

First, Parke-Davis argued that allowing Franklin to use the FCA to enforce the FD&C Act would create a cause of action for money damages under the Act, and thus circumvent its enforcement provisions by providing the FDA with a tool not prescribed in the Act itself.³⁰³ In considering this argument, the court acknowledged that the FCA “cannot be used to enforce compliance with every federal law or regulation.”³⁰⁴ However, the FCA “*can* be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentation made to obtain a government benefit.”³⁰⁵ Thus, taking the allegations of Franklin’s complaint as true, the court found that the fact that Congress did not “provide a cause of action for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude an FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government.”³⁰⁶

³⁰¹ *Id.* at 50 (citing *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 788 (4th Cir. 1999)).

³⁰² *Id.* at 51.

³⁰³ *Id.* The court noted that the FD&C Act only allows the FDA to enforce the off-label marketing ban through seizures, injunctions, and criminal proceedings, but does not provide for civil damage remedies. *Id.*

³⁰⁴ *Id.*

³⁰⁵ *Id.*

³⁰⁶ *Id.* at 52.

Second, Parke-Davis argued that off-label promotion does not necessarily include a false statement or fraudulent conduct, as in the case of a technical violation of the off-label marketing bans.³⁰⁷ The court found this argument inapplicable to Franklin’s complaint, however, because Parke-Davis’ alleged FCA violation was not based on the off-label marketing activity itself but rather on the manufacturer’s “course of fraudulent conduct including knowingly making false statements to doctors that caused them to submit claims that were not eligible for payment by the government under Medicaid.”³⁰⁸ The court acknowledged that a more difficult question would exist if Franklin had only alleged unlawful, but truthful, off-label promotion of Neurontin.³⁰⁹

Third, Parke-Davis claimed that Franklin’s allegations could not meet the FCA’s causation requirement because the independent actions of the physicians who wrote the off-label prescriptions and the pharmacists who accepted and filled the off-label prescriptions broke the chain of legal causation.³¹⁰ The district court rejected this argument as well, noting that as a matter of law an intervening force only breaks a causal connection if it is unforeseeable.³¹¹ Here, however, “the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.”³¹²

Finally, the district court rejected Parke-Davis’ argument that Franklin had not alleged that false statements made by the manufacturer were material to the government’s decision to pay the claims for off-label Neurontin prescriptions.³¹³ The court found that the fact that the prescriptions were for an off-label use was

³⁰⁷ *Id.*

³⁰⁸ *Id.*

³⁰⁹ *Id.*

³¹⁰ *Id.*

³¹¹ *Id.*

³¹² *Id.* at 52-53.

³¹³ *Id.* at 53.

material because “the government would not have paid the claims if it had known the use for which they were being submitted.”³¹⁴ Thus, Franklin had sufficiently alleged that Parke-Davis “caused-to-be-presented” false claims through a fraudulent course of conduct in violation of section 3729(a), given the expansive statutory language of the FCA and the Supreme Court’s consistent refusal “to accept a rigid, restrictive reading’ of the FCA.”³¹⁵

The district court thus dismissed each of Parke-Davis’ arguments against Franklin’s theory of FCA liability and allowed his *qui tam* suit to proceed. In doing so, the court accepted that Franklin’s particular allegations might present an appropriate claim for an FCA violation, that is a manufacturer may violate the FCA by engaging in a fraudulent course of conduct designed to induce doctors to prescribe an FDA-approved drug for an off-label use, knowing that these prescriptions would result in the submission of claims to the federal government for Medicaid reimbursement.

Motion for Summary Judgment Decision

Parke-Davis again challenged Franklin’s allegations and theory of FCA liability with a motion for summary judgment, which the district court denied on August 22, 2003.³¹⁶ In this motion, Parke-Davis argued that Franklin had to prove “that Parke-Davis intentionally made a material false statement that led to the filing of a false claim” in order to claim liability under the FCA.³¹⁷ Parke-Davis thus interpreted the FCA as containing a “double falsehood requirement: An FCA plaintiff must prove a false statement that led to a false claim,” and argued that Franklin had not shown that Parke-Davis made any material false statements.³¹⁸ The district court rejected this legal argument as inconsistent with the text of the FCA, clarifying that while section 3729(a)(2) of the FCA contains a double-falsehood requirement, only one falsehood is required under

³¹⁴*Id.*

³¹⁵*Id.* (citing *United States v. Neifert-White Co.*, 390 U.S. 228, 232-33 (1968)).

³¹⁶*United States ex rel. Franklin v. Parke-Davis*, 2003 U.S. Dist. LEXIS 15754 at *1.

³¹⁷*Id.* at *3.

³¹⁸*Id.*

section 3729(a)(1) of the FCA.³¹⁹

The court thus found that Franklin was “not required to present evidence that Parke-Davis lied to physicians about Neurontin’s off-label efficacy or safety to induce them to prescribe Neurontin for uses ineligible under Medicaid” because his FCA claim was not limited to section 3729(a)(2).³²⁰ Acknowledging that its opinion on Parke-Davis’ motion to dismiss focused on allegations of false statements under section 3729(a)(2), the district court went on to determine that under section 3729(a)(1) “the only issue is whether Parke-Davis ‘caused to be presented’ a false claim, and section 3729 does not require that the ‘cause’ be fraudulent or otherwise independently unlawful.”³²¹

The district court then addressed Parke-Davis’ attack on Franklin’s claim that an off-label prescription submitted for reimbursement by Medicaid is a false claim within the meaning of the FCA, which Parke-Davis had previously not disputed.³²² Parke-Davis argued that forty-two states’ Medicaid programs “permit reimbursement for off-label, non-compendium drug prescriptions, and that therefore claims for Medicaid reimbursement for off-label Neurontin prescriptions in those states were not false claims.”³²³ In contrast, Franklin argued that the Medicaid statute did not authorize states to provide such broad coverage, but instead only gave the states discretion within the category of “covered outpatient drugs.”³²⁴ The district

³¹⁹ *Id.* Section 3729(a)(2) creates liability for anyone who “knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government.” Section 3729(a)(1), however, provides for liability where a defendant “knowingly presents or causes to be presented . . . a false or fraudulent claim.” *Id.* The district court cited precedent establishing that liability under section 3729(a)(1) does not require the additional element of an express false statement, as required for liability under section 3729(a)(2). *Id.* (citing *Shaw v. AAA Eng’g & Drafting, Inc.*, 213 F.3d 519, 531 (10th Cir. 2000) and *United States ex rel. Fallon v. Accudyne Corp.*, 921 F. Supp. 611, 627 (W.D. Wis. 1995)).

³²⁰ *United States ex rel. Franklin v. Parke-Davis*, 2003 U.S. Dist. LEXIS 15754 at *4.

³²¹ *Id.* at *5.

³²² *Id.* at *6.

³²³ *Id.* at *7. Parke-Davis claimed that under 42 U.S.C. §1396r-(8)(d)(1)(B), “states have the option not to exclude coverage for drugs for which the prescribed use is not for a medically accepted indication.” *Id.*

³²⁴ *Id.* at *7-8. The court considered Franklin’s interpretation unlikely because it made subsection 1396r-(8)(d)(1)(B)(i) superfluous, in violation of basic rules of statutory construction. *Id.* at *8.

court found this debate to be immaterial however, because Parke-Davis conceded “that eight states do not provide reimbursement for off-label drug prescriptions not included in a medical compendium,” and in those states, such a Medicaid reimbursement request would therefore be a false claim.³²⁵ Parke-Davis’ argument thus pertained to the amount of damages, rather than to Franklin’s ability to demonstrate a false claim, and the court declined to consider damages at the summary judgment stage.³²⁶

Parke-Davis raised a further factual argument in its motion for summary judgment, claiming that because the Medicaid reimbursement claim forms for prescription drugs do not require the claimant to list the use for which the drug is being prescribed, Franklin could not show that any Medicaid claims sought reimbursement for off-label uses.³²⁷ The district court rejected this argument, however, finding that Franklin had provided sufficient analysis “linking patients’ treatment histories to Neurontin prescriptions that generated reimbursement claims” to survive summary judgment.³²⁸

Parke-Davis again attacked Franklin’s ability to demonstrate the requisite causal connection between Parke-Davis’ actions and the false claims at issue, claiming that Franklin could not show that Parke-Davis “either exerted ‘control over’ or otherwise directly influenced, the submission of a false claim” because of the role of doctors, patients, and pharmacists in the submission of Medicaid reimbursement claims.³²⁹ In considering this claim, the district court applied common law tort causation concepts, which would require Franklin to show both (1) that Parke-Davis’ conduct was a “substantial factor” in causing the presentation of false Medicaid claims, and (2) that Parke-Davis could have foreseen false Medicaid claims being filed.³³⁰ The court found that the first requirement was a question of fact, as to which Franklin had produced enough evidence to survive summary judgment.³³¹ As to the foreseeability requirement, the district court reiterated

³²⁵*Id.* at *9-10.

³²⁶*Id.* at *10.

³²⁷*Id.*

³²⁸*Id.* at *10-11.

³²⁹*Id.* at *11.

³³⁰*Id.* at *12-13.

³³¹*Id.* at *13.

that it had already held that Parke-Davis could have foreseen false Medicaid claims being filed in its motion to dismiss opinion, and further stated that Franklin had “provided evidence that Parke-Davis’ actions were not irrelevant, but rather played a key role in setting in motion a chain of events that led to false claims.”³³² Finally, the district court addressed the government’s argument that “Parke-Davis’ alleged violation of the Medicaid Antikickback provision caused false claims, because Medicaid claimants impliedly certify that their claims have not been tainted by kickbacks.”³³³ While the court found the government’s argument persuasive, it declined to revive Franklin’s claim of Antikickback violations because the government was still not a party to the suit.³³⁴ Instead, the court indicated that evidence of kickbacks could be relevant to Franklin’s allegations that Parke-Davis violated section 3729(a)(1) of the FCA by “causing-to-be-presented” claims for reimbursement for off-label prescriptions that were ineligible for coverage under Medicaid.

Legal Theories Underscoring *Franklin v. Parke-Davis*

Franklin’s FCA claim presented an unprecedented legal theory – an attempt to hold a pharmaceutical manufacturer liable to the US government for moneys paid out to reimburse Medicaid claims because the manufacturer’s promotion resulted in those claims being improperly filed. In denying Parke-Davis’ motion to dismiss and motion for summary judgment, the District of Massachusetts indicated that this novel attempt may be a valid one, given the particular facts alleged in Franklin’s complaint. At the motion to dismiss stage, the court’s acceptance of Franklin’s theory seemed to turn on his allegations of false statements and fraudulent conduct on the part of Parke-Davis in promoting off-label uses of Neurontin.³³⁵ However, the district court’s summary judgment opinion gave potential support to a broader theory of liability under

³³²*Id.* at *13, 16.

³³³*Id.* at *19.

³³⁴*Id.* at *20.

³³⁵United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d at 52.

section 3729(a)(1) of the FCA when it stated that “the only issue [was] whether Parke-Davis ‘caused to be presented’ a false claim, and §3729 does not require that the ‘cause’ be fraudulent or otherwise independently unlawful.”³³⁶ The court thus indicated that a manufacturer may violate section 3729(a)(1) of the FCA by promoting an FDA-approved drug for off-label use, even if such promotion is truthful, if it knows that the promotion will foreseeably result in the submission of claims for Medicaid reimbursement that are not reimbursable under the Medicaid statute because they are not for a medically accepted indication.

Assessing whether this unprecedented legal theory is, in fact, sound requires considering the intersection of the two subjects previously addressed – the FDA’s approach to off-label uses of prescription drugs and the purposes and requirements of the FCA – to determine whether and how the alleged conduct satisfies the required elements of an FCA claim. While the district court in *Franklin v. Parke-Davis* found Franklin’s legal theory to be valid given the specific facts he alleged, the validity of such a claim may not be as definite in other factual scenarios. A plaintiff in a future case alleging FCA liability based on manufacturer promotion of off-label uses might have a harder time demonstrating, as required, that: “(1) the ‘person’; (2) ‘present[ed]’ or ‘cause[d] to be presented’; (3) ‘a false or fraudulent’; (4) ‘claim,’ ‘record or statement’; (5) ‘knowingly’; (6) to ‘the United States [government]’; that was (7) ‘material’ to the government’s determination to pay.”³³⁷ Thus, considering some of the difficult questions involved with this legal theory is important to understanding its potential future impact. Decisions in future cases attempting to extend Franklin’s theory of FCA liability will likely raise a number of legal questions – specifically, is a pharmaceutical manufacturer an appropriate defendant in a suit based on false claims submitted for Medicaid reimbursement? Furthermore, are claims submitted for Medicaid reimbursement of prescriptions for off-label indications actually false or fraudulent?

³³⁶United States *ex rel.* Franklin v. Parke-Davis, 2003 U.S. Dist. LEXIS 15754 at *6.

³³⁷HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 117-18.

Finally, even if a plaintiff's allegations actually meet the requisite elements for an FCA claim, is the FCA an appropriate tool for the prevention of manufacturer promotion of off-label uses of FDA-approved drugs?

Manufacturer Cause-to-be-Presented Liability

An initial question may seem to exist as to whether a pharmaceutical manufacturer is appropriate defendant in an FCA action based on improper reimbursement of Medicaid claims for off-label prescriptions given the fact that the manufacturer did not actually submit the claims for reimbursement. However, if a qui tam plaintiff is able to prove the requisite level of scienter for an FCA claim on the part of the manufacturer, the manufacturer is a proper defendant to such an action because of the "cause-to-be-presented liability" provided for in section 3729(a)(1) of the FCA.³³⁸ Such liability is widely accepted in FCA jurisprudence, and normally applies "where the person responsible for the falsity does not actually submit the claim, but rather directs others (who may not know of the falsity) to submit the claim on his or her behalf."³³⁹

In the scenario involved in *Franklin v. Parke-Davis*, the chain of events that leads to the payment of a false claim for Medicaid reimbursement involves several links: a manufacturer markets a drug to doctors, who prescribe it for their patients, who take the prescriptions to their pharmacists, who file claims for Medicaid reimbursement.³⁴⁰ The potential FCA liability of each of these parties involved in submitting the false claim is tied to their individual scienter rather than to their proximity to the actual submission in the chain of causation. The FCA defines "knowingly" to mean that a party "(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard

³³⁸31 U.S.C. §3729(a)(1).

³³⁹Krause, *supra* note 112, at 140.

³⁴⁰United States *ex rel.* Franklin v. Parke-Davis, 2003 U.S. Dist. LEXIS 15754 at *11.

of the truth or falsity of the information.”³⁴¹ In the *Franklin v. Parke-Davis* scenario, to act “knowingly” a defendant would have to be aware that a submitted claim was not properly reimbursable under Medicaid because it was not for a medically accepted indication, act in deliberate ignorance of this information, or act with reckless disregard for this information.³⁴² If a plaintiff were unable to prove this level of scienter as to an individual defendant, the defendant could not be liable under the FCA.³⁴³

A plaintiff’s ability to prove scienter as to an individual defendant in the *Franklin v. Parke-Davis* scenario will likely be a very fact-intensive inquiry. The patient who submits the prescription to be filled might not know if s/he is prescribed a drug for an unapproved use and probably is not aware of the technicalities of the Medicaid laws. The pharmacist might act with the requisite scienter if s/he is aware that a particular unapproved use is not reimbursable under Medicaid, and knows the patient well enough to determine whether the particular prescription was for an approved or unapproved use. Thus, although both the patient and the pharmacist are closely linked in the chain of causation to the actual submission of the false claim for reimbursement, they may not have acted with the scienter required for FCA liability. And, although their relation to the submission of the false claim is more tenuous, either physicians or manufacturers might be shown to have acted with the requisite scienter because they would be aware of a drug’s approved and unapproved uses and of the requirements for reimbursement under the Medicaid laws. The physician or pharmaceutical manufacturer’s liability would turn on whether the plaintiff could show that the potential defendant knew the claim would be submitted for Medicaid reimbursement.

If the plaintiff could demonstrate the requisite scienter as to either the physician or the pharmaceutical manufacturer, those parties could only be liable through §3729(a)(1)’s special provision for “cause-to-be-presented” liability because of the attenuated nature of their relationship to the actual submission of the

³⁴¹ 31 U.S.C. §3729(b).

³⁴² *Id.*

³⁴³ *Id.*

false claim for Medicaid reimbursement. In order to rely on “cause-to-be-presented” liability, a plaintiff will likely have to show that the manufacturer directed or authorized the submission of the improper claim for Medicaid reimbursement.³⁴⁴ If the plaintiff can only show that the manufacturer ‘knew’ that the claims would be improperly submitted for Medicaid reimbursement but did not actually direct the submission, a court may not find that “cause-to-be-presented” liability is proper.³⁴⁵ In *Franklin v. Parke-Davis*, Franklin alleged that:

when questions arose concerning the availability of reimbursement for prescriptions for off-label uses of Parke-Davis drugs, medical liaisons were instructed to coach doctors on how to conceal the off-label nature of the prescription. Relator also alleges that Parke-Davis took numerous actions to conceal its activities from the FDA, including shredding documents, falsifying documents, and encouraging medical liaisons to conduct their marketing activities without leaving a “paper trail” that might be discovered by the FDA.³⁴⁶

These allegations, if supported by evidence, are probably crucial to Franklin’s ability to support “cause-to-be-presented” liability on the part of Parke-Davis because they indicate that Parke-Davis directed the submission of false claims.³⁴⁷ However, if a plaintiff were unable to show that a drug manufacturer engaged in similar activities, s/he might not be able to recover based on “cause-to-be-presented” liability.³⁴⁸

Future plaintiffs’ ability to demonstrate FCA liability on the part of drug manufacturers based on “cause-to-be-presented” liability may have drastic impacts on drug manufacturers’ promotional activities. The policy implications of the potential impacts are discussed in Part V below, but at this point it is worth noting that manufacturers may attempt to find means of limiting their FCA liability. For instance, if a manufacturer includes a disclaimer about Medicaid reimbursability in a drug’s package insert, patients will likely have a harder time demonstrating that the manufacturer acted “knowingly” or directed the submission of false

³⁴⁴HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 117, n.31.

³⁴⁵*Id.* (citing *United States ex rel. Shaver v. Lucas Western Corp.*, 237 F.3d 932, 933 (8th Cir. 2001)).

³⁴⁷HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 117, n.31.

³⁴⁸*Id.*

claims, as required by the FCA.³⁴⁹

The Falsity of Claims Submitted for Medicaid Reimbursement

Liability under the FCA clearly requires that the claims submitted to the government for payment are ‘false’ or ‘fraudulent,’ which begs the question of whether claims submitted for Medicaid reimbursement of off-label prescriptions are actually ‘false’ or ‘fraudulent.’³⁵⁰ At the motion to dismiss stage in *Franklin v. Parke-Davis*, the parties did not dispute that off-label prescriptions submitted for reimbursement by Medicaid are false claims within the meaning of the FCA.³⁵¹ Later, at the summary judgment stage, Parke-Davis raised an argument that such claims were not actually false because of the discretion permitted in states by the Medicaid statute to provide reimbursement for off-label, non-compendium drug prescriptions.³⁵² The district court rejected this argument, pointing to the fact that in eight states there is no discretion for reimbursement for off-label prescriptions not included in a medical compendium such that Medicaid reimbursement requests for off-label, non-compendium prescriptions in those states constitute false claims.³⁵³

The district court in *Franklin v. Parke-Davis* has thus far accepted that claims Medicaid reimbursement of off-label prescriptions may constitute false claims, and based on the court’s opinions, some literature has accepted that although such claims are infrequent, they may actually be false within the meaning of the FCA.³⁵⁴ In particular, Joel M. Androphy and Mark A. Corroero have posited that “if a governmental Medicaid or Medicaid program pays for...non-approved uses, a false claim arises.”³⁵⁵ In support of this

³⁴⁹31 U.S.C. §3729(b); HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 117, n.31.

³⁵⁰31 U.S.C. §3729(a)(1).

³⁵¹United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d at 51.

³⁵²United States *ex rel.* Franklin v. Parke-Davis, 2003 U.S. Dist. LEXIS 15754 at *7.

³⁵³*Id.*

³⁵⁴Krause, *supra* note 110, at 1390; Androphy & Corroero, *supra* note 120, at 43-45.

³⁵⁵Androphy & Carrero, *supra* note 120, at 43.

statement, Androphy and Carrero theorize that if a manufacturer disseminates information on off-label uses in a manner that does not meet the requirements of the FDAMA, a drug is misbranded because it is accompanied by literature concerning unapproved uses, and the manufacturer promotion of the off-label use is impermissible under the FD&C Act.³⁵⁶ This explanation ignores the significant First Amendment implications of manufacturer promotion of off-label uses, discussed above. Furthermore, Androphy and Carrero's explanation seems to confuse two separate issues involved in determining whether such claims are indeed false – the FDA prohibition on manufacturer promotion of off-label uses and the technicalities of what constitutes a properly reimbursable claim under the Medicaid laws.

As discussed above, the Supreme Court has stated that “the False Claims Act was not designed to reach every kind of fraud practiced on the Government;”³⁵⁷ however, “now, with only a few exceptions, most conduct that illegally increases payment by the government of revenues to which it is entitled, has been held (correctly or not) to trigger FCA liability.”³⁵⁸ Given the expansive interpretation of “false” that most courts currently apply in FCA cases, the district court correctly accepted Franklin's argument at summary judgment that claims for off-label prescriptions submitted for Medicaid reimbursement, at least in those states where there is no discretion to reimburse off-label, non-compendium uses, are indeed false.³⁵⁹ Such claims are false because they induce the government to reimburse for prescriptions not properly reimbursable under the Medicaid statute, in the same way that claims are false when health care providers perform unnecessary medical services and seek reimbursement for them by certifying that they were medically necessary.³⁶⁰ By “causing-to-be-presented” claims that should not rightly be reimbursed under the Medicaid statutes of at

³⁵⁶*Id.* at 44.

³⁵⁷*United States v. McNinch*, 356 U.S. 595 (1958).

³⁵⁸BOESE, *supra* note 165, at §2, 2-5 (citing *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d at 788).

³⁵⁹Androphy & Carrero, *supra* note 120, at 37; *United States ex rel. Franklin v. Parke-Davis*, 2003 U.S. Dist. LEXIS 15754 at *7.

³⁶⁰Bucy, *supra* note 149, at 81.

least 8 states, manufacturers may have violated the FCA by leading the government to pay out money improperly.

Androphy and Carrero’s argument that claims for Medicaid reimbursement of off-label prescriptions are false simply because the manufacturer is prohibited from promoting the off-label use under the FD&C Act seems less straightforward. As discussed in Part I above, the FDA does take the approach that manufacturer promotion of off-label use can violate both the misbranding and the new drug approval requirements of the FD&C Act.³⁶¹ In addition, FDA regulations specifically prohibit manufacturers from advertising off-label uses of their approved products.³⁶² However, the FDA’s current approach to enforcement, reflected in *Washington Legal Foundation v. Henney* and the FDA’s Final Guidance for Industry on CME, is that a manufacturer’s noncompliance with the FDAMA or CME Guidance safe harbors does not, by itself, constitute a violation of the FD&C Act, although such noncompliance may be used as evidence in a misbranding or “intended use” enforcement action.³⁶³ Furthermore, based on the district court decision in *Washington Legal Foundation v. Henney* that addresses the First Amendment implications of the FDAMA and the CME Guidance, FDA would likely have difficulty asserting that either of those sources provided an independent ground for enforcement because neither meets the *Central Hudson* test for constitutionally permissible restrictions on commercial speech.³⁶⁴

Androphy and Carrero may thus be incorrect that a manufacturer who promotes an off-label use of an approved drug inherently breaks the law. Furthermore, even if a manufacturer’s conduct violates the FD&C Act, such conduct does not necessarily lead to a false claim for purposes of the FCA if it does not result in

³⁶¹Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. at 64,075-76.

³⁶²21 C.F.R. §202.1(e)(4)(i)(a).

³⁶³WLF v. Henney, 202 F.3d at 335-36.

³⁶⁴WLF v. Henney, 56 F. Supp. 2d at 87.

the submission of a claim for Medicaid reimbursement that is not properly reimbursable under the statute. As Parke-Davis argued and the district court acknowledged at the summary judgment stage, the Medicaid programs of forty-two states allow for discretion to reimburse for off-label, non-compendium uses.³⁶⁵ In those states, a manufacturer may promote a drug for an off-label use in violation of the FD&C Act, and that promotion may result in the submission of claims for Medicaid reimbursement for prescriptions; however, if the state Medicaid program allows discretion to reimburse the claim regardless of its off-label nature, no false claim exists.

In the eight states where Medicaid programs do not allow for such discretion, submissions of claims for Medicaid reimbursement for off-label uses may potentially constitute false claims under the FCA.³⁶⁶ A manufacturer who promoted a drug for an off-label use, knowing that it would result in an improper claim for Medicaid reimbursement might thus be held liable under the FCA in one of those states. However, in defending against such liability, the drug manufacturer might argue that its promotional behavior was protected by the First Amendment. Thus, a court ruling on an allegation of FCA liability on the part of a drug manufacturer for promoting off-label uses that resulted in improper claims for Medicaid reimbursement would be forced to balance the competing policies underlying the FCA and the First Amendment.

The FCA as a Tool For Enforcing the FD&C Act

The situation described above, where a manufacturer may violate the FD&C Act by promoting a drug for an off-label use but where that promotion does not result in the submission of a false claim for Medicaid reimbursement, raises the issue of whether the FCA is an appropriate tool for enforcing the FD&C Act.

³⁶⁵United States *ex rel.* Franklin v. Parke-Davis, 2003 U.S. Dist. LEXIS 15754 at *7.

³⁶⁶*Id.*

The FD&C Act provides the government with a number of enforcement remedies – administrative seizures, injunctions, and criminal proceedings – but does not provide the FDA with a civil damage remedy for violations.³⁶⁷ Policing FD&C Act violations through the FCA would thus allow for an otherwise unavailable civil damage remedy. However, courts have widely acknowledged that, “violations of laws, rules, or regulations alone do not create a cause of action under the FCA.”³⁶⁸ Instead, liability arises under the FCA where “failure to abide by a rule or regulation amounts to a material misrepresentation made to obtain a government benefit.”³⁶⁹

The district court in *Franklin v. Parke-Davis* rejected Parke-Davis’ argument that Franklin’s claim was an inappropriate end-run around the FD&C Act enforcement provisions, stating:

The failure of Congress to provide a cause of action for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude an FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government in violation of 31 U.S.C. §3729(a).³⁷⁰

Thus, in the *Franklin v. Parke-Davis* scenario, Parke-Davis’ allegedly fraudulent conduct “caused-to-be-presented” false claims for Medicaid reimbursement, giving rise to FCA liability. Hypothetically, however, a manufacturer may actually violate the FD&C Act by promoting a drug for an off-label use, but this promotion may not necessarily result in a technically false claim, perhaps because of the discretion in a state’s Medicaid program. In such a case, the manufacturer’s violation of the FD&C Act, in and of itself, would likely be insufficient to constitute a violation of the FCA.³⁷¹ Given courts’ caution that, “the FCA is

³⁶⁷21 U.S.C. §§332 (a), 333(a).

³⁶⁸*United States ex rel. Hopper v. Anton*, 91 F.2d 1261, 1266-67 (9th Cir. 1996).

³⁶⁹*United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d at 51.

³⁷¹*See e.g. United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 416 (3d. Cir. 1999) (“Not every regulatory violations is tantamount to making a knowingly false statement to the government.”).

not an appropriate vehicle for policing technical compliance with administrative regulations,”³⁷² an FD&C Act violation that does not result in a false claim could be viewed as the type of regulatory violation that does not inherently give rise to FCA liability.³⁷³ In that situation, Congress’ failure to provide for civil monetary penalties for FD&C Act violations could provide further evidence that the FCA was an inappropriate tool for enforcing such violations.³⁷⁴

Using the FCA as a means of enforcing the FD&C Act may also be inappropriate in situations where the reimbursement of claims for off-label uses has no impact on the public treasury. Joan H. Krause argues that the concept of “harm to the public fisc” should guide the application of the FCA to the health care industry in order to cloak it with legitimacy.³⁷⁵ She posits that the concept of “harm to the public fisc” provides not only a method of calculating damages and the extent of a defendant’s liability, but also a means of deciding whether a case merits use of the FCA at all.³⁷⁶ As discussed above, there are many hypothetical situations in which a manufacturer may violate the FD&C Act by improperly promoting off-label prescriptions of an approved drug but this promotion does not result in any government expenditure or direct harm to the public treasury. For instance, when an off-label prescription is written for a patient covered by private insurance, the manufacturer’s underlying conduct may violate the FD&C Act, but no government expenditure results and FCA liability for the manufacturer is thus clearly inappropriate. This logic may apply as well in the scenario raised in *Franklin v. Parke-Davis*, where claims are submitted for Medicaid reimbursement in a state that allows discretion in covering off-label, non-compendium uses. In that situation, the lack of harm

³⁷²United States *ex rel.* Lamers v. City of Green Bay, 168 F.3d 1013, 1020 (7th Cir. 1999).

³⁷³Hopper v. Anton, 91 F.2d at 1266-67.

³⁷⁴21 U.S.C. §§332(a), 333(a).

³⁷⁵Krause, *supra* note 112, at 126-27. Krause uses the term “public fisc” to refer to the public treasury.

³⁷⁶*Id.* at 126.

to the public treasury may provide further evidence that the FCA is an inappropriate enforcement tool.³⁷⁷

Policy Implications of *United States ex rel. Franklin v. Parke-Davis*

V.

In addition to presenting a novel legal claim, *Franklin v. Parke-Davis* raises potential policy implications. First, a decision holding the manufacturer liable under the FCA could have a disparate impact on Medicaid beneficiaries as opposed to privately insured individuals, which might be important in light of the Medicare Prescription Drug Benefit that will go into effect in 2006. Next, the decision in *Franklin v. Parke-Davis* may have an effect on manufacturer's willingness to disseminate information about off-label uses, even pursuant to the FDAMA or the CME Guidance, which in turn would impact physicians' ability to provide optimal medical care to patients. Finally, *Franklin v. Parke-Davis* highlights the clash between FDA policy on manufacturer promotion of off-label uses and the First Amendment because manufacturers may seek to assert First Amendment defenses to suits under the FCA.

Disparate Impact on Medicaid Beneficiaries

If *Franklin v. Parke-Davis* successfully establishes the manufacturer's liability under the FCA for its promotion of off-label uses of prescription drugs, the decision could potentially have a negative effect on Medicaid beneficiaries' ability to gain access to such off-label prescriptions. This effect might be particularly troublesome, given that off-label prescriptions are most often used in oncology and in pediatrics, areas of medicine that may require more cutting-edge treatments.³⁷⁸

³⁷⁷ *Id.*

³⁷⁸ *WLF v. Friedman*, 13 F. Supp. 2d at 56.

A decision that the manufacturer is liable under the FCA for promotion of off-label uses of approved drugs that results in the submission of claims for Medicaid reimbursement could send a message to the drug manufacturers that they should limit such promotion if Medicaid claims may result. Drug manufacturers, seeking to limit their liability, could therefore decline to provide information on off-label uses to physicians whom they know to extensively treat Medicaid patients. Disseminations of information by drug manufacturers via enduring materials and CME seminars permitted under the FDAMA and the CME Guidance provide a great deal of the necessary information available to physicians on off-label uses.³⁷⁹ Thus, if drug manufacturers limited the availability of such information to physicians treating Medicaid patients for fear of FCA liability, those Medicaid patients would be much less likely to receive possibly life-saving off-label prescriptions. Although, as noted above, many states' Medicaid programs provide discretion for coverage of off-label, non-compendium uses, drug manufacturers might choose not to involve themselves with Medicaid physicians at all rather than risk promotion in one of the states that does not allow such discretion. And, while there is a narrow exception in the Medicaid statute that allows for payment for certain drugs that are not otherwise covered where the drugs have been determined to be "essential to the health of the beneficiaries," drug manufacturers might again choose to err on the side of caution.³⁸⁰

Medigap, Medicare+Choice, and Medicare Part D plans (under the Medicare Prescription Drug Benefit that will go into effect in 2006) are or will be administered through contracts between private insurers and the Secretary of HHS which provide for risk sharing arrangements with the federal government.³⁸¹ As discussed in greater detail in Part II, all of these plans provide for some form of government reinsurance payments of prescription drug costs paid by the plan or enrollee.³⁸² Because all of these plans potentially implicate

³⁷⁹Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. at 64,076.

³⁸⁰42 U.S.C. §1396r-8(a)(3).

³⁸¹*Prescription Drug Coverage for Medicare Beneficiaries* at 7, <http://www.kff.org>.

³⁸²*Id.* at 3, <http://www.kff.org>.

the public treasury, improperly submitted claims for reimbursement under any of them might be found to constitute a basis for FCA liability in the same manner as improperly submitted Medicaid reimbursement claims in *Franklin v. Parke-Davis*. Thus, while a decision in *Franklin* would be limited on its facts to claims submitted for Medicaid reimbursement, the reasoning of the case might be extended to any or all of Medigap, Medicare+Choice, and Medicare Part D plans. Pharmaceutical manufacturers seeking to limit their potential FCA liability might therefore exhibit similar caution in dealing with physicians treating any Medicare beneficiaries following a decision upholding liability in *Franklin v. Parke-Davis*.

In contrast, however, private insurance companies' prescription drug coverage is largely determined by their formularies.³⁸³ In fifteen states, private insurers must allow beneficiaries access to non-formulary drugs if (1) they are medically necessary, (2) they are prescribed by a physician, and (3) the preferred drug is ineffective or reasonably expected to cause an adverse or harmful reaction.³⁸⁴ Fifteen states also require coverage of non-formulary drugs when scientific results reported in the medical literature support the off-label use of a drug for a medical condition, and "an additional 15 states specifically require[d] off-label coverage for the treatment of cancer."³⁸⁵ Thus, privately insured individuals may automatically have greater access to off-label prescriptions than do Medicaid beneficiaries by virtue of state law.

Furthermore, the potential chilling effects of *Franklin v. Parke-Davis* on drug manufacturers' willingness to promote off-label uses to Medicaid physicians would not extend to physicians who treated privately insured individuals because such promotion could not give rise to FCA liability. While the logic of *Franklin* might be extended, as discussed above, to Medigap, Medicare+Choice, or Medicare Part D claims, claims submitted for reimbursement by private insurers cannot provide the basis for FCA liability because they do not involve

³⁸³*How do M+C Plans Manage Pharmacy Benefits? Implications for Medicare Reform* at 12, <http://www.kff.org>.

³⁸⁴DESCRIPTION AND ANALYSIS OF THE VA NATIONAL FORMULARY, *supra* note 236, at 153.

³⁸⁵*Id.*

claims presented for payment to the federal government.³⁸⁶ Promotion of off-label uses to physicians treating privately insured individuals might potentially be actionable by the FDA under the FD&C Act, but would not lead to the false claims necessary to trigger the FCA's application. Thus, while drug manufacturers might curb their promotion of off-label uses to Medicaid physicians (and even to Medicare physicians) in an effort to stem their FCA liability, they would not have to do the same with regards to physicians treating the privately insured. Again, given the fact that off-label prescriptions are most often written in oncology and pediatrics, a decision upholding manufacturer liability in *Franklin v. Parke-Davis* could have a significant impact on Medicaid beneficiaries' access to cutting-edge medical treatment.

Manufacturer Willingness to Disseminate Information

In addition to the potential concentrated impact on Medicaid populations, a decision holding the manufacturer liable in *Franklin v. Parke-Davis* might affect the larger patient population as well. A manufacturer that fears incurring FCA liability based on disseminated information on off-label uses might choose to limit the information it makes available to physicians. As discussed above, a manufacturer might only restrict information available to Medicaid physicians because false claims, and hence FCA liability, can only arise from Medicaid (and perhaps Medicare) claims. However, an extremely cautious or risk-averse manufacturer might reduce or altogether eliminate its disseminations of information on off-label uses to all physicians, not just to those treating Medicaid or Medicare patients. Clearly a manufacturer cannot be held liable for any improperly submitted Medicaid claims if it has not disseminated information on the off-label use for which the prescription is written because it has not played any role in the chain of causation that led to

³⁸⁶31 U.S.C. §3729(a).

the improper submission. Thus, the manufacturer could not be shown to have “caused-to-be-presented” the false claim for payment, as required for FCA liability.³⁸⁷

This approach would have a drastic effect on physicians’ ability to provide optimal medical care to patients given the fact that disseminations of information by drug manufacturers via enduring materials and CME seminars provide a great deal of the necessary information available to physicians on off-label uses.³⁸⁸ Without information on the effectiveness of off-label uses, physicians would not be able to prescribe drugs for cutting-edge uses, and the impact would likely be most severely felt in the areas of oncology and pediatrics. Manufacturers may, however, hesitate to restrict their disseminations in such a severe manner because off-label uses represent such a high proportion of overall drug sales – estimates state that between 25 and 65% of all prescriptions written are for an off-label use.³⁸⁹ If physicians did not receive information on the safety and efficacy off-label uses, they would be much less likely to prescribe drugs for such uses, and the overall sales of drugs for off-label uses would drop accordingly. Thus, drug manufacturers seeking to maintain their current sales levels would most likely balance the risks of FCA liability based on disseminations of information on off-label uses against the benefits of sales that result from such disseminations.

This calculus would most likely lead drug manufacturers to attempt to limit disseminations of such information only to physicians treating Medicaid (and possibly Medicare) patients, as FCA liability cannot arise from off-label prescriptions written for privately insured individuals. Such a distinction, however, could be extremely difficult to implement in practice. Thus, if manufacturers found themselves unable to differentiate between physicians along these lines, they could opt to err on the side of caution by reducing or eliminating their disseminations of information on off-label uses to all physicians, with resulting deleterious effects on physicians’ ability to provide optimal medical care to patients.

³⁸⁷31 U.S.C. §3729(a)(1).

³⁸⁸Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. at 64,076.

³⁸⁹Blackwell & Beck, *supra* note 5, at 440 (citing Shane M. Ward, *WLF and the Two-Click Rule: The First Amendment Iniquity of the Food and Drug Administration’s Regulation of Off-Label Drug Use Information on the Internet*, 56 FOOD & DRUG L.J. 41, 45-46 (2001)).

Clash Between FCA Liability and the First Amendment

Franklin v. Parke-Davis also raises an interesting policy question about the role that the First Amendment should play as a defense to an action under the FCA. As discussed above, a plaintiff's ability to show that a manufacturer is liable under the FCA for promotion of off-label uses of approved drugs that results in improperly submitted claims for Medicaid reimbursement will turn significantly on the facts of the particular case. However, if a plaintiff is able to make the requisite showings to establish FCA liability, the manufacturer-defendant may in turn seek to assert a defense based on the First Amendment, claiming that its promotional activities constitute protected speech. In response, the plaintiff could attempt to rebut this defense by distinguishing between the manufacturer's promotional activities themselves and the intent behind those promotional activities. The manufacturer's FCA liability would stem from the actions it took to promote its drug for off-label uses "knowing" that the use was not properly reimbursable under Medicaid; FCA liability would not inhere to manufacturer promotional activities absent a showing of the requisite levels of scienter and direction of submission of claims.³⁹⁰ Thus, the plaintiff might concede that the manufacturer's promotion was protected insofar as it was not aimed at causing the submission of false claims, but argue that promotion accompanied by the requisite intent for FCA liability falls outside the scope of First Amendment protection. The court faced with the burden of deciding the case would thus have to balance the competing policies behind the FCA and the First Amendment in determining whether the First Amendment could properly shield the manufacturer from FCA liability.

VI.

³⁹⁰31 U.S.C. §3729(b).

Conclusion

United States ex rel. Franklin v. Parke-Davis represents the intersection of two threads of food and drug law that had previously been independent – the regulation of promotion of off-labels uses of FDA-approved drugs and the Medicare and Medicaid fraud and abuse laws, most notably the civil False Claims Act. As discussed in Part IV, the district court has thus far approved Franklin’s attempts to use the FCA as a means of creating manufacturer liability for off-label promotion by rejecting both Parke-Davis’ motion to dismiss and motion for summary judgment.³⁹¹ Both decisions have, however, depended largely on the specific facts that Franklin alleged concerning the extent of Parke-Davis’ fraudulent activity. In considering the possible future ramifications of *Franklin v. Parke-Davis*, it is important to note that its value as precedent may be limited by the emphasis the district court ultimately places on the specific facts of Franklin’s allegation in its final decision on the case. If the opinion turns largely on the details of those factual allegations, a future qui tam plaintiff seeking to assert *Franklin v. Parke-Davis* as the basis for similar manufacturer liability may find him/herself in a more difficult position in terms of proving the requisite elements of an FCA claim.

In particular, depending on the facts of his/her individual case, a future plaintiff may have difficulty asserting a number of elements of an FCA claim, as discussed in Part IV. First, the plaintiff may have difficulty proving that the manufacturer “caused to be presented” false claims for payment by the government if s/he could not show that the manufacturer directed the claims be submitted but only “knew” that they would be submitted.³⁹² Next, a plaintiff may not be able to show that the claims submitted were “false or fraudulent”

within the meaning of the FCA, perhaps because the applicable state Medicaid statute provides discretion

³⁹¹*United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d at 39; *United States ex rel. Franklin v. Parke-Davis*, 2003 U.S. Dist. LEXIS 15754 at *1.

³⁹²HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, *supra* note 109, at 117, n.31.

in reimbursement for off-label, non-compendium uses.³⁹³ A plaintiff may face further resistance from a court as to whether the FCA is an appropriate tool for enforcing the off-label promotion provisions of the FD&C Act, either because the promotion has not resulted in a false claim or because the claim has not resulted in harm to the public treasury, and the FD&C Act does not provide a civil damages remedies for violations. Finally, the manufacturer may seek to assert a defense based on the First Amendment, forcing the court to determine whether the manufacturer's promotional speech merited First Amendment protection given an intent to "cause-to-be-submitted" false claims under the FCA.

In addition to these fact-based issues, which future plaintiffs will surely face in claiming manufacturer FCA liability based on promotion of off-label uses, the legal claim involved in *Franklin v. Parke-Davis* raises the interesting policy considerations discussed in Part V. In considering the extension of FCA liability in this manner, courts should perhaps be informed by the potential disparate impact their decisions could have on Medicaid (and even Medicare) populations as opposed to privately insured individuals. Courts faced with future cases raising claims similar to those in *Franklin v. Parke-Davis* should remain cognizant of the crucial role that manufacturer dissemination of information on off-label uses plays in ensuring that physicians have access to the cutting-edge research needed to provide patients with optimal medical care. A thorough evaluation of these potential impacts clearly requires much more in-depth analysis, however, it is important to remember that cases are not decided in a vacuum and may have vast and far-reaching social consequences in addition to their value as legal precedent.

³⁹³United States *ex rel.* Franklin v. Parke-Davis, 2003 U.S. Dist. LEXIS 15754 at *7.